

## Meeting Minutes

April 17, 2023 | 10:00 am - 12:00 pm

Virtual Zoom Only Meeting

Member attendance					
Sen. Ron Muzzall	N	Dr. Josh Frank	Y	Dr. Ricardo Jimenez	N
Sen. Annette Cleveland	N	Joelle Fathi	N	Dr. Geoff Jones	Y
Rep. Marcus Riccelli	N	Kathleen Daman	N	Scott Kennedy	Y
Rep. Joe Schmick	Y	Dr. Frances Gough	Y	Mark Lo	Y
Dr. John Scott	Y	Lisa Woodley	Y	Heidi Brown	Y
Dr. Chris Cable	Y	Emily Stinson	Y	Adam Romney	Y
Jae Coleman	N	Sheryl Huchala	Y	Cara Towle	N
Stephanie Cowen	N	Amy Pearson	Y	Lori Wakashige	Y

Non-Member Presenters: Ashby Wolfe (CMS), Cindy Jacobs (UW & ITHS), Bradford Felker (VA Puget Sound), Hanna Dinh Hsieh (UWM)

Public attendees (alphabetical by first name):

Al Hansell (CHPW), Alesia Black (Clearwater Counseling), Avanti Bergquist (unknown), Brittainy Wittg-Valieva (FHCC), Cara Carlton (MultiCare), Chris Liles (Seattle Children's), Clark Hansen (ALS), Dan Dodd (Antioch Community Counseling & Psychology), Deanette James (unknown), Erin Abood (Stanford Medicine), Gail McGaffick (WSPMA), Gayle Rundstrom (National MS Society), Hanna Jones (unknown), Hillary Norris (WSMA), Jeb Shepard (WSMA), Jim Freeburg (Patient Coalition of WA), Jodi Kunkel (HCA), Josh Viggers (UWM), Julia O'Connor (WA Council for Behavioral Health), Kai Neander (EHMC), Kara Shirley (Clinical Pharmacy Consultant LLC), Karen Salmon (Diligent Medical Billing), Leslie Emerick (WA State Hospice and Palliative Care), Lisa Roche (Providence), Maia Thomas (DCYF ESIT), Mandy Latchaw (DOH), Marissa Ingalls (Coordinated Care), Marjorie Parkison (UWM), Marshall Bishop (unknown), Marshall Glass (Boulder Care), Matt Landers (FHCC), Melissa Rieger (Craig Hospital), Michelle Lin (UWM), Mike Zwick (Cambia Health), Mylinh Nguyen (WSPA), Nicki Perisho (NRTRC), Nicole Pauly (Mindful Therapy Group), Nomie Gankhuyag (FHCC), Patrick Hastings (Bird's Eye Medical), Rachel Abramson (UWM), Rachel Ferguson (MultiCare Indigo), Relief Mental Health, Remy Kerr (WSHA), Sabrina Lin (UW), Sarah Koca (CHPW/CHNW), Shannon Thompson (WMHCA), Sondra Hornsey (Stanford Health Care), Tammie Perreault (WA Department of Defense), Thalia Cronin (CHPW), Tracy Mikesell (DOH).

# WashingtonState TelehealthCollaborative

Meeting began at 10:00 am

## Welcome and Attendance

Dr. John Scott [[0:00](#)]

## Review of Meeting Minutes - January 9, 2023

Dr. John Scott [[4:46](#)]

Dr. Scott (Chair) reviews minutes. Dr. Chris Cable (Kaiser Permanente) motioned to approve minutes. Dr. Joshua Frank (Confluence Health) seconded. Unanimously approved as submitted.

### **Action Item:**

- Mrs. Dinh Hsieh (Collaborative Program Manager) to post approved January 2023 notes on WSTC website

## State/Federal Updates

Hanna Dinh Hsieh and Dr. John Scott (UWM) [[8:46](#)]

### **State Update**

- On March 30, [S.B. 5036](#) was passed, which is an act that extends the time frame in which real-time telemedicine using both audio and video technology may be used to establish a relationship for providing audio-only telemedicine for health care services other than behavioral health.
  - Effective July 23, 2023
  - After July 1, 2024, the appointment must take place in person
- The thought behind this was that we'd hear back from the Office of the Insurance Commissioner and the UW Medicine Value & Systems Science Lab (VSSL) group regarding the cost impact of audio only and some of the concerns around fraud, abuse, and driving up costs.
  - The plan is to have some data to present in the coming months to see if this bill should be permanently extended or have some changes made.

### **Federal Updates**

- Effective February 11, the Department of Health & Human Services extended the federal COVID-19 public health emergency (PHE) an additional 90 days through 5/11/2023. The Biden Administration declared that the PHE will end on 5/11/2023.
  - Declaration of renewal [here](#).
- 2 resources provide an overview of the major health-related COVID-19 federal emergency declarations and summarizes the flexibilities triggered in various areas, including telehealth, along with their status updates post-PHE.
  - Kaiser Family Foundation (KFF) brief [here](#).

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- Association of American Medical Colleges overview [here](#).
- The Drug Enforcement Administration (DEA) announced proposed rules for permanent telemedicine flexibilities regarding prescribing controlled substances, titled [Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation](#). Public comment was closed on March 31.
  - DEA's press release [here](#).
  - Summary of proposed rules [here](#).
- An extension of [The Telehealth Expansion Act \(H.R. 5981\)](#) was introduced, which makes permanent a waiver created by the CARES Act in allowing Americans with Health Savings Accounts (HSAs) to access telehealth services without first having to meet their deductible.
- [The Connecting Students with Mental Health Services Act](#) would create a federal grant program to help school districts fund telehealth programs that provide mental health services for improving access to care for students, including in rural and low-income school districts.

## State Telehealth Training Updates

- At the last Collaborative meeting, one of the presenters, Dr. Felker shared best practices in telehealth training. One of the action items was sharing the Collaborative's state telehealth training with him for review and feedback.
- The state telehealth training has been updated per Dr. Felker's feedback, specifically around informed consent and safety planning.

## Questions/Discussion

- Dr. John Scott adds that there were about 60,000 comments from the public regarding the DEA proposed rules on telemedicine prescribing of controlled substances. A final rule is expected in late April/early May.
- Will these slides be available?
  - All the slides from today's Collaborative meeting except for Dr. Wolfe's slides and the meeting's recording will be available on the Collaborative website: <https://www.wsha.org/policy-advocacy/issues/telemedicine/washington-state-telemedicine-collaborative/meetings-and-minutes/>

## CMS Telehealth Policy Updates

Dr. Ashby Wolfe (CMS) [[15:27](#)]

## Disclaimer

- This presentation was prepared as a tool to assist providers and is not intended to grant rights or impose obligations. Although every reasonable effort has been made to assure the accuracy of the information within these pages, the ultimate responsibility for the correct submission of claims and response to any remittance advice lies with the provider of services.
- This publication is a general summary that explains certain aspects of the Medicare Program, but is not a legal document. The official Medicare Program provisions are contained in the relevant

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laws, regulations, and rulings. Medicare policy changes frequently, and links to the source documents have been provided within the document for your reference

- The Centers for Medicare & Medicaid Services (CMS) employees, agents, and staff make no representation, warranty, or guarantee that this compilation of Medicare information is error-free and will bear no responsibility or liability for the results or consequences of the use of this presentation.

## Objectives

- CMS Telehealth Policy Overview and Update
- Review how CMS policies will change following the end of the COVID-19 public health emergency
- Questions

## COVID-19 Emergency Declaration

- January 31, 2020—U.S. Department of Health & Human Services (HHS) Secretary declares PHE
- March 13, 2020—National Emergency Declaration
- Together, these actions authorize the HHS Secretary to waive certain Medicare, Medicaid, Children's Health Insurance Program (CHIP), and Health Information Portability and Accountability Act (HIPAA) requirements

## Duration of Public Health Emergency (PHE)

- The PHE declaration and each renewal lasts 90 days
- Secretary notifies Congress to extend PHE
- HHS has pledged to give states 60 days notice prior to expiration
- The COVID-19 PHE was declared on January 31, 2020 and has been renewed numerous times since then.
- On January 30, 2023, the Biden Administration announced **its intent to end the national emergency and public health emergency declarations on May 11, 2023**, related to the COVID-19 pandemic.
- <https://www.cms.gov/coronavirus-waivers>
- <https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html>

## Medicare Telehealth Benefit

- Definition of Medicare Telehealth
  - Medicare telehealth services are services ordinarily furnished in person that are instead furnished via a telecommunications system and are subject to geographic, site of service, practitioner, and technological restrictions
  - Section 1834(m)(4)(F) of the Social Security Act (the Act) defines telehealth services as professional consultations, office visits, and office psychiatry services, and any additional services specified by the Secretary

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- 1834(m) also requires CMS to establish a process for adding or deleting services from the list of telehealth services on an annual basis
- These services must be performed by a physician or other health care practitioner

## Beyond Medicare Telehealth

- CMS makes separate payment for many other services that utilize telecommunications technology
- The statutory restrictions do not apply to these services, even though they may utilize telecommunications technology
- Examples include:
  - Care Management Services
  - Communication Technology-Based Services
  - E-visits
  - Virtual Check-in
  - Remote Physiologic Monitoring

## Conditions of Coverage for Medicare Telehealth Services (*before the COVID-19 Public Health Emergency*)

- **Technology Requirements**
  - Interactive telecommunications system
  - Does not include telephone, fax, or email
- **Geographic Restrictions**
  - Patient must be located in a Rural Health Professional Shortage Area located outside of a Metropolitan Statistical Area or in a rural census tract
- **Authorized Originating Sites**
  - Office of a physician or practitioner, hospital, critical access hospital (CAH), rural health clinic, federally qualified health center, hospital-based or CAH-based renal dialysis centers (including satellites), skilled nursing facility, and community mental health center

## Changes to Medicare Telehealth Policy & COVID-19

- Effective for dates of services starting March 6, 2020 and for the duration of the COVID-19 PHE, Medicare pays for telehealth services furnished to patients in broader circumstances
  - 1135 Waiver (Effective for services starting March 6, 2020): **Waived both geographic and site of service restrictions** so beneficiaries in all areas of the country can receive telehealth services, including at home
  - 1135 Waivers (Effective for services starting March 1, 2020): **Waived restrictions on the types of practitioners** that can furnish Medicare telehealth services and **Waived video requirement** to allow use of audio-only equipment for certain Medicare telehealth services
  - These **visits are considered the same as in-person visits and are paid at the same rate** as regular, in-person visits

### Current Medicare Telehealth Flexibilities Under the COVID-19 Public Health Emergency (PHE)

- **Eligible Practitioners**
  - All health care practitioners who are authorized to bill Medicare for their professional services may also furnish and bill for telehealth services
  - Healthcare professionals who weren't previously authorized under the statute to furnish and bill for Medicare telehealth services may receive payment for Medicare telehealth services
- **Audio-only Telehealth for Certain Services**—as of March 1, 2020, telephone evaluation, management, and certain behavioral health care and educational services may be furnished via telehealth using audio-only telephones

### Calendar Year 2021 Changes

- **Highlights:**
  - Added 9 services to the Medicare telehealth list on a Category 1 basis (similar to services already on the telehealth list)
  - Created a temporary third category of criteria for adding services to the list of Medicare telehealth services (services added to the Medicare telehealth list during the PHE that will remain on the list through the calendar year in which the PHE ends)—added 58 services
  - Clarified that licensed clinical social workers, clinical psychologists, physical therapists (PTs), occupational therapists (OTs), and speech-language pathologists (SLPs) can furnish the brief online assessment and management services as well as remote evaluation services and virtual check-ins via 2 new HCPCS codes, G2010 and G2012

### Services CMS Finalized in 2021 as Permanent Medicare Telehealth Services

- Group psychotherapy
- Domiciliary, rest home, or custodial care services, established patients
- Home visits, established patient
- Cognitive assessment and care planning services
- Visit complexity inherent to certain office/outpatient evaluation management (E/Ms)
- Prolonged services
- Psychological and neuropsychological testing

### Calendar Year 2022 Changes: Telehealth & Other Services Involving Communications Technology (1)

- **Mental Health (Consolidated Appropriations Act (CAA))**
  - Section 123 of the CAA **removed the geographic restrictions and added the home of the beneficiary as a permissible originating site** for telehealth services when used for the purposes of diagnosis, evaluation, or treatment of a mental health disorder
  - Also **requires that there be an in-person, non-telehealth service with the physician or practitioner within 6 months prior to the initial telehealth service**, and thereafter, at intervals as specified by the Secretary

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- We're implementing these statutory amendments, and finalizing that **an in-person, non-telehealth visit must be provided at least every 12 months** for these services, that exceptions to the in-person visit requirement may be made based on beneficiary circumstances (with the reason documented in the patient's medical record), and that **more frequent visits are also allowed under our policy**, as driven by clinical needs on a case-by-case basis

## Calendar Year 2022 Changes: Telehealth & Other Services Involving Communications Technology (2)

- CMS is **updating the definition of interactive telecommunications** system for telehealth services to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients in their homes under certain circumstances
- CMS is **limiting the use of an audio-only interactive telecommunications system to mental health services** when the beneficiary isn't capable of, or doesn't consent to, the use of two-way, audio/video technology
- CMS also finalized a requirement for the **use of a new modifier for services given using audio-only communications**, which verifies the practitioner had the capability to provide two-way, audio/video technology but, used audio-only technology due to beneficiary choice or limitations. We're also clarifying that **mental health services can include services for treatment of substance use disorders (SUDs)**

## Calendar Year 2022 Changes: Telehealth & Other Services Involving Communications Technology (3)

- **CMS will extend, through the end of CY 2023, the inclusion on the Medicare telehealth services list of certain services added temporarily** to the telehealth services list that would otherwise have been removed from the list as of the later of the end of the COVID-19 PHE or December 31, 2021. (This will allow CMS additional time to evaluate if the services should be permanently added to the Medicare telehealth services list)
- We also have extended inclusion of certain cardiac and intensive cardiac rehabilitation codes through the end of CY 2023
- Additionally, CMS is adopting coding and payment for a longer virtual check-in service on a permanent basis

## Temporary Additions to Telehealth

- Domiciliary, rest home, or custodial care services, established patients
- Home visits, established patient
- Emergency department visits, Levels 1–5\*
- Nursing facilities discharge day management
- Psychological and neuropsychological testing
- Therapy services, physical and occupational therapy, all levels\*
- Hospital discharge day management\*
- Inpatient neonatal and pediatric critical care, subsequent\*

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- Continuing neonatal intensive care services\*
- Critical care services\*
- End-Stage Renal Disease Monthly Capitation Payment codes\*
- Subsequent Observation and Observation Discharge Day Management\*
- \* Services that were not proposed as Category 3 additions to the Medicare telehealth list but are being finalized as such.

## Calendar Year 2023 Physician Fee Schedule Final Rule: Telehealth and Other Services Involving Communications Technology (1)

- **Telehealth Services List**
  - For CY 2023, we finalized a number of policies related to Medicare telehealth services:
  - Making **several services that are temporarily available as telehealth services for the PHE available at least through CY 2023** in order to allow additional time for collection of data that may support their inclusion as permanent additions to the Medicare Telehealth Services List.
  - Extending the duration of **time that services are temporarily included on the telehealth services list during the PHE for at least a period of 151 days following the end of the PHE**, in alignment with the Consolidated Appropriations Act, 2022 (CAA, 2022).
- <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes>

## Calendar Year 2023 Physician Fee Schedule Final Rule: Telehealth and Other Services Involving Communications Technology (2)

- **Other Telehealth Policies**
  - We finalized the proposal to allow physicians and practitioners to continue to bill with the place of service (POS) indicator that would have been reported had the service been furnished in-person.
    - These claims will require the modifier “95” to identify them as services furnished as telehealth services.
    - Claims can continue to be billed with the place of service code that would be used if the telehealth service had been furnished in-person through the later of the end of CY 2023 or end of the year in which the PHE ends.
  - The Telehealth Originating Site Facility Fee has been updated for CY 2023, which can be found with the list of Medicare Telehealth List of Services at the following website: <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes>

## Consolidated Appropriations Act, 2023

- **The Consolidated Appropriations Act, 2023, extended many Medicare telehealth flexibilities through December 31, 2024**, such as:
  - People with Medicare can access telehealth services in any geographic area in the United States, rather than only those in rural areas.



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- People with Medicare can stay in their homes for telehealth visits that Medicare pays for rather than traveling to a health care facility.
- Certain telehealth visits can be delivered audio-only (such as a telephone) if someone is unable to use both audio and video, such as a smartphone or computer.
- <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes>
- <https://www.cms.gov/files/document/what-do-i-need-know-cms-waivers-flexibilities-and-transition-forward-covid-19-public-health.pdf>

## Consolidated Appropriations Act, 2023 (2)

- For Medicaid and CHIP, telehealth flexibilities are not tied to the end of the PHE and have been offered by many state Medicaid programs long before the pandemic. Coverage will ultimately vary by state.
- To assist states with the continuation, adoption, or expansion of telehealth coverage, CMS has released the State Medicaid & CHIP Telehealth Toolkit and a supplement that identifies for states the policy topics that should be addressed to facilitate widespread adoption of telehealth:
- <https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit-supplement1.pdf>

## Data related to use of Telehealth during the COVID-19 Pandemic

- **Increased Use of Telehealth & Medications for Opioid Use Disorder During the COVID-19 Pandemic Reduced Risk of Fatal Overdose**
  - March 29: Collaborative research by CMS, the Centers for Disease Control and Prevention (CDC), and National Institute on Drug Abuse (NIDA) revealed that **the expanded availability of opioid use disorder-related telehealth services and medications during the COVID-19 pandemic lowered the likelihood of fatal drug overdose** among Medicare beneficiaries.
  - The findings were published in a joint CMS, CDC, and NIDA manuscript in [JAMA Psychiatry](#).

## Acute Hospital Care at Home

- There is a current waiver that CMS supports known as the Acute Hospital Care at Home Waiver
  - This was developed at the end of 2020 to assist hospitals primarily with the COVID-19 surge and to allow hospitals that had an approved waiver to treat appropriately selected patients at an inpatient level in their homes
  - This represented the first time that CMS would be paying for this kind of care under Medicare fee-for-service and in some cases, non-managed Medicaid reimbursement
- This waiver is not directly telehealth, but there are hospitals across the country that are leveraging telehealth services to support the inpatient care in their homes
- Under the Consolidated Appropriations Act of 2023, this waiver has been extended for another 2 years – will continue through December 31<sup>st</sup>, 2024

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- Hospitals can continue to apply for this waiver approval and if approved, an individual can continue participating as an inpatient at home as long as they meet the requirements of the waiver
- In Washington State, there are four hospitals that have current approved waivers, including MultiCare's Tacoma General Hospital, MultiCare's Good Samaritan Hospital, Providence St. Peter Hospital, and St. Joseph's Medical Center
  - You can see which hospitals have been approved in the following link:  
<https://qualitynet.cms.gov/acute-hospital-care-at-home>
- You can also read some preliminary data via a study that was published in the New England Journal Catalyst last December: <https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0338>
- Dr. Ashby Wolfe is also one of the co-leads for this waiver team – she can be one of the CMS contacts to connect with regarding this waiver

## Summary: Telehealth policy changes after the COVID-19 Public Health Emergency

- **Permanent Medicare changes**
  - Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) can serve as a distant site provider for behavioral/mental telehealth services
  - Medicare patients can receive [telehealth services for behavioral/mental health care](#) in their home
  - There are no geographic restrictions for originating site for behavioral/mental telehealth services
  - Behavioral/mental telehealth services can be delivered using audio-only communication platforms
  - Rural hospital emergency departments are accepted as an originating site
- <https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency>

## Summary: Telehealth policy changes after the COVID-19 Public Health Emergency (2)

- **Temporary Medicare changes through December 31, 2024 (Consolidated Appropriations Act, 2023)**
  - Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) can serve as a distant site provider for non-behavioral/mental telehealth services
  - Medicare patients can receive telehealth services authorized in the [Calendar Year 2023 Medicare Physician Fee Schedule](#) in their home.
  - There are no geographic restrictions for originating site for non-behavioral/mental telehealth services
  - Some non-behavioral/mental telehealth services can be delivered using audio-only communication platforms
  - An in-person visit within six months of an initial behavioral/mental telehealth services, and annually thereafter, is not required
  - Telehealth services can be provided by a physical therapist, occupational therapist, speech language pathologist, or audiologist.

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- <https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency>

## Summary: Telehealth policy changes after the COVID-19 Public Health Emergency (3)

- **Temporary changes through the end of the COVID-19 public health emergency**
  - Telehealth can be provided as an [excepted benefit](#)
  - Medicare-covered providers may use any [non-public facing application](#) to communicate with patients without risking any federal penalties – even if the application isn't in compliance with the [Health Insurance Portability and Accountability Act of 1996 \(HIPAA\)](#)
- **CMS recently published policy updates for Medicare telehealth services**
  - CMS clarified that temporary telehealth services added during the COVID-19 Public Health Emergency (PHE) will continue through the end of Calendar Year 2023
  - Telehealth services [provided in the office setting](#) will continue to be paid at the non-facility rate (higher payment) through the end of Calendar Year 2023
  - CMS will not implement new codes for [remote therapeutic monitoring \(RTM\)](#) as initially proposed
- <https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency>

## Resources to Help the Health Care Industry Prepare

- CMS has created 16 provider-specific fact sheets for information about COVID-19 PHE waivers and flexibilities, including those:
  - Already terminated
  - Made permanent
  - That will terminate with the end of the PHE
  - Clarifies payment policies following the end of the PHE
  - See these updated fact sheets at: <https://www.cms.gov/coronavirus-waivers>
  - Summary of policy changes (to date): <https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency>
- Additional Telehealth guidance, as well as guidance specific to the COVID-19 Public Health Emergency, found here: <https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page>
- Additional FAQs and other materials regarding the **Consolidated Appropriations Act 2023** telehealth policies will be forthcoming. <https://www.cms.gov/files/document/what-do-i-need-know-cms-waivers-flexibilities-and-transition-forward-covid-19-public-health.pdf>

## Contact Information

- Ashby Wolfe, MD, MPP, MPH
- Centers for Medicare & Medicaid Services
- CMS Offices in Seattle & San Francisco
- [ashby.wolfe1@cms.hhs.gov](mailto:ashby.wolfe1@cms.hhs.gov)
- 415-680-0013

### Questions/Discussion

- Do these changes also cover Medicaid, or are the Medicaid telehealth rules different than the Medicare rules?
  - These changes are specific to Medicare Telehealth Policy. There is a Medicaid toolkit that is particularly useful to review the current rules for Medicaid. Ultimately, coverage will vary by state Medicaid program. Please see:  
<https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit-supplement1.pdf>
- Can you clarify if the addition of PT, OT, and ST as eligible providers, and those codes, are for professional services facilities billing on a UB04 vs. only for those who are a professional service billed out on a 1500? Can these folks provide telehealth services in a hospital-based clinic vs. clinic-based locations?
  - When it comes to a clinician who is based in a hospital, when the public health emergency ends, the billing will change. Part of the logistics behind this change is going to be included in their FAQ document that is responding to the new Consolidated Appropriations Act of 2023.
    - The clinician can continue to bill as if they were providing the service to the patient in a clinical setting – the place of service code can remain the same
    - However, the hospital component of the telehealth service must go back to the way it was prior to the public health emergency
    - There will be clinical scenarios developed in the FAQ document to hopefully help provide clarity on who should be billing for what service and when, as the public health emergency ends
  - They can currently bill for telehealth services as they have been under the COVID-19 Public Health Emergency and will be able to do so through December 31, 2024 as authorized by the Consolidated Appropriations Act of 2023. CMS will be issuing an FAQ to address billing for hospital-based vs. community-based clinicians in the near future. Please see: <https://www.cms.gov/coronavirus-waivers> for current rules regarding clinician billing, and FAQs forthcoming.
- If a behavioral health beneficiary opts for audio only when audio-visual was available, does this affect the reimbursement for that visit?
  - In the way the requirement and the regulation is written, there is a modifier that can be used by the clinician if the beneficiary chooses not to participate in the video component of the telehealth service. The clinician can add that modifier into their billing and they can still bill for the telehealth service as if it were provided in an audio video manner.
  - There is one scenario where the technology is not working and the video component option is not functional, but there is also the scenario where the beneficiary chooses not to have the video component where you can convert to an audio only and use that modifier on the claim.
- What is the modifier as referenced in the previous question?
  - All billing/coding details for providing telehealth services are found here: <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth>

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- For those seeking mental health care via telehealth, if they are receiving a controlled substance they will need to be seen within 6 months of their first telehealth visit and then, once a year thereafter?
  - For those seeking mental health services via telehealth, an in-person visit within six months of an initial behavioral/mental telehealth service, and annually thereafter, is not required (as a result of the Consolidated Appropriations Act of 2023). Please see: <https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency>
- In teaching settings where residents are providing telehealth with the teaching physician, what is the expectation for in-person supervision for the key & critical components of the visit? Will the resident and teaching physician need to be in the same room, same telehealth session?
  - Regarding virtual supervision of medical trainees, the ending of that flexibility is two-fold and not related to the December 2024 extension. CMS is working on developing additional guidance that will be forthcoming. In the meantime, please see page 4 of our current [document related to Teaching Hospitals, Physicians and Residents](#) also found here: <https://www.cms.gov/coronavirus-waivers>, and excerpted below:
    - “Teaching physicians involving residents in providing care at certain primary care centers can provide the necessary direction, management, and review for services furnished by up to four residents at a time using audio/video real-time communications technology. **After the PHE, teaching physicians only in residency training sites located outside of a metropolitan statistical area may direct, manage, and review care furnished by residents through audio/video real-time communications technology.** During the PHE, teaching physicians can oversee and bill for an expanded scope of care furnished by up to four residents at a time in certain primary care centers, including all levels of an office/outpatient evaluation and management (E/M) visit, telephone E/M, care management, and communication technology-based services. **After the PHE, teaching physicians can bill for levels 4-5 of an office/outpatient evaluation and management (E/M) visit furnished by residents in these primary care centers only when the teaching physician is physically present for the key portion of the service.”**
- Will there be no new remote therapeutic monitoring (RTM) codes, or are the existing ones being suspended?
  - CMS will not implement new codes for RTM as initially proposed. Please see: <https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency>
- Dr. Ashby Wolfe adds the following:
  - You can find the transcript and recording from the April 12 CMS Physician Open Door Forum, which includes lots of Q&A regarding billing/coding for telehealth, when it is posted here: <https://www.cms.gov/outreach-and-education/outreach/opendoorforums/podcastandtranscripts>
    - The information is typically posted about 2 weeks after the event date

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- For CMS rules, the following are PERMANENT changes that will not be affected by the end of the PHE on May 11:
  - Medicare patients can receive telehealth services for behavioral/mental health care in their home
  - There are no geographic restrictions for originating site for behavioral/mental telehealth services
  - Behavioral/mental telehealth services can be delivered using audio-only communication platforms.
  - See: <https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency>
- A new FAQ document is now available at the top of the following page – updated 4/26/2023: <https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page>

## **Action Items:**

- Add Medicaid telehealth policies in Washington state as a future topic for a Collaborative meeting
- If the Collaborative members have any further questions, reach out to Dr. Ashby Wolfe at [ashby.wolfe1@cms.hhs.gov](mailto:ashby.wolfe1@cms.hhs.gov).

## **Remote Prescribing of Controlled Substances**

Adam Romney (Davis Wright Tremaine LLP) [[48:36](#)]

### **Ryan Haight Online Pharmacy Consumer Protection Act**

- The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 requires a telemedicine provider to perform an **in-person medical evaluation** of a patient **prior to prescribing a controlled substance** to that patient, unless an exception applies (21 U.S.C. § 829(e)(1)).
- The Act includes an exemption to the in-person medical evaluation requirement for the delivery, distribution or dispensing of a controlled substance by a practitioner engaged in the “**practice of telemedicine**” (21 U.S.C. § 829(e)(3)).
- However, the “practice of telemedicine” is defined quite narrowly. Specifically, it is defined as an encounter that is provided in one of **seven circumstances**.

### **Seven “Practice of Medicine” Circumstances**

- The patient is being treated in and is physically located in a hospital or clinic.
- The patient is being treated by and in the physical presence of another practitioner.
- The patient is being treated by a provider employed by the Indian Health Services.
- The treatment is occurring **during a PHE**... as designated by HHS and the US Attorney General.
- The patient is being treated by a practitioner who holds a **special registration**...
- There is a medical emergency and the patient is being treated by an employee of the Veterans Health administration....

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- The patient is being treated under **other circumstances as set forth in regulation** as determined jointly by the HHS Secretary and the US Attorney General...

## “Special Registration”

- The “special registration” could establish a criteria, process or other circumstances under which controlled substance prescribing could occur without a prior in-person visit.
- The DEA has not defined “special registration” in **14 years**.
- In the 2018 SUPPORT for Patients and Communities Act, Congress imposed a deadline of October 2019 for the DEA to define the “special registration”

## March 16, 2020: PHE Exception for Telemedicine Prescriptions

- The DEA waived the Ryan Haight Act requirement that a practitioner prescribing controlled substances over the internet must have conducted at least one “in-person medical evaluation” of the patient
- Prescribers may issue prescriptions pursuant to a telemedicine encounter for all schedule II-V controlled substances if:
  - Issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice
  - The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system
  - The practitioner is acting in accordance with applicable Federal and State laws
- **Expires May 11, 2023**

## February 24, 2023: DEA Proposed Rules

- DEA publishes two Proposed Rules on Friday, February 24, 2023
  - The Telemedicine Controlled Substance Proposed Rule
  - The Telemedicine Buprenorphine Proposed Rule
- Includes three new options for telemedicine prescribing of controlled substances without a prior in-person medical exam
  - The options are more limiting than the DEA’s PHE waiver
  - The proposed rules still do not address “special registration” for telemedicine
  - Instead, the DEA relied on subparagraph G (i.e., the 7th circumstance)
- The Proposed Rules closed for public comment on March 31, 2023

## New Options under Proposed Rules

- Option 1: Telemedicine Encounter for a Limited Supply of Schedule III, IV or V Controlled Substances
- Option 2: Qualifying Telemedicine Referral
- Option 3: Buprenorphine via Telemedicine Encounter

## Definition of “Telemedicine Encounter”

- Means an encounter conducted as defined by 42 CFR 410.78(a)(3):
  - “...multimedia communications equipment that includes, at a minimum, **audio and video** equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.
  - “For services furnished for purposes of diagnosis, evaluation, or treatment of a **mental health disorder** to a patient in their home, interactive telecommunications may include two-way, **real-time audio-only** communication technology if the distant site physician or practitioner is technically capable to use an interactive telecommunications system as defined in the previous sentence, but the patient is not capable of, or does not consent to, the use of video technology.”
- The term “mental health disorder” includes “substance use disorder

**Definition: “Telemedicine Relationship During the COVID-19 Public Health Emergency**

- Means:
  - When a prescriber **has not** conducted as an in-person medical evaluation of the patient,
  - But conducted a telemedicine encounter **during the PHE**, and
  - Conducted the encounter in compliance with the DEA’s waiver requirements
- Facilitates a six-month transition of doctor-patient relationships established during the PHE
  - **Expires Nov. 7, 2023**

**Option 1: Telemedicine Encounter for a Limited Supply**

- Allows practitioners to prescribe non-narcotic Schedule III-V controlled substances when:
  - The telemedicine encounter is for a legitimate medical purpose with a prescriber acting in the usual course of professional practice
  - The prescriber is located in the U.S.
  - The prescriber is authorized to prescribe in their state and the patient’s state
  - The prescriber reviews the state’s PDMP records for the past 12 months
  - The prescriber notates the prescription to indicate it was issued pursuant to a telemedicine encounter

**Option 1: Telemedicine Encounter for a Limited Supply**

- Excludes Schedule II controlled substances
- Limited to a 30-day supply (no renewals)
- Limited to a 7-day supply if the PDMP is nonoperational or unavailable, and the prescriber documents:
  - When they attempted to access the PDMP
  - Why they could not gain access to the PDMP
  - Any follow-up attempts to access the PDMP

**Option 1: Record Keeping**



- For each prescription issued pursuant to these rules, a prescriber must maintain records of the following:
  - Date the prescription was issued
  - Full name and address of the patient
  - Drug name, strength, dosage form, quantity and directions for use
  - Addresses of the prescriber and patient during the telemedicine encounter
  - All efforts to comply with the requirement of accessing the PDMP system

#### **Option 2: Qualifying Telemedicine Referral**

- What is a “Qualifying Telemedicine Referral”?
  - A referral by a practitioner who has conducted at least one in-person exam of a patient
  - To another practitioner who conducts a telemedicine exam of such patient
  - The referral is made for a legitimate medical purpose in the ordinary course of their professional practice

#### **Option 2: Qualifying Telemedicine Referral**

- Allows prescriptions of controlled substances (including beyond a 30-day supply) if:
  - The prescriber receives a “qualifying telemedicine referral”
  - From a DEA registered practitioner
  - Who has conducted an in-person exam of the patient

#### **Option 2: Recording Keeping (Prescriber)**

- For each prescription issued pursuant to Option 2, a prescriber must maintain the same records as Option 1, plus:
  - The name and NPI of the referring practitioner
  - A copy of the referral and any communications shared

#### **Option 2: Record Keeping (Referring Practitioner)**

- For each prescription issued pursuant to Option 2, a referring practitioner must maintain records of the following:
  - The data and time of the evaluation
  - The NPI of the DEA-registered practitioner physically present with the patient
  - The address at which the prescribing practitioner is located during the telemedicine encounter
  - The address at which the DEA-registered practitioner was physically present with the patient during the medical evaluation

#### **Option 3: Buprenorphine via Telemedicine Encounter**

- Allows buprenorphine prescriptions via telemedicine encounters when:
  - For use in the maintenance and detoxification treatment of opioid-use disorder (only)
  - Prescriber maintains a DEA registration in prescriber’s state

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- Prescriber is authorized to practice telemedicine in the patient's and the prescriber's state (i.e., complies with state law, including modality limitations)
- Prescriber must comply with DEA and Controlled Substances Act requirements applicable to maintenance and detoxification treatment
- Prescriber must be capable of using synchronous audio-video
- Prescriber must review the state's PDMP prior to prescribing buprenorphine

### Option 3: Buprenorphine via Telemedicine Encounter

- Some requirements are the same as Option 1:
  - 30-day / 7-day limits (no renewals)
  - Record keeping requirements
- Audio-only permitted (if “the patient is not capable of, or does not consent to, the use of video technology”)

### Takeaways

- Re-establishes many pre-pandemic barriers to care: Geographic, socioeconomic, technology
- Some telehealth providers do not have physical space to conduct in-person visits
- No Schedule II prescriptions without an in-person evaluation
- New options and grandfathering may conflict with state law
- Statutory “Special Telemedicine Registration” exception is still undefined
- Creates a “telemedicine cliff” for some patients
  - Opioid treatment
  - Pain
  - ADHD
  - Sleep Disorders
  - Panic and Anxiety
  - Epilepsy
  - Other

### Questions/Discussion:

- Dr. Ashby Wolfe (CMS) clarifies that CMS does not retain control over the FDA policies in this presentation
- Dr. John Scott shares that schedule II medicines include narcotics (e.g. morphine, oxycodone, etc.), which means that chronic pain patients will be affected by this change
  - Dr. Mark Lo (Seattle Children's) adds that schedule II medicines also include stimulants for conditions like ADHD, which means that behavioral/mental health patients are also impacted
- If a provider is cross-covering for their colleague who is out of the office, can this provider write prescriptions for their colleague's patients?
  - Yes, the Ryan Haight Act has always had some cross-covering language. If the provider conducted the in-person evaluation and they are on leave/vacation, someone else can fill

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in and write a prescription for a limited period of time. However, the act is limited to this scenario.

- There have been folks who have thought creatively on how to use this cross-covering language in a broader way.
- Is it just option 1 that will require the prescriber to be in the U.S. or does this apply to all options?
  - Adam Romney (Davis Wright Tremaine) states that he will need to follow-up on this question.
- Dr. John Scott shares that it's not just telehealth-only providers who are challenged by physical space – all systems have repurposed those spaces and it's not easy to revert back prior to 2020.

## **Action Item:**

- If the Collaborative members have any further questions, reach out to Adam Romney at [adamromney@dwt.com](mailto:adamromney@dwt.com).

## **AI and Machine Learning FDA Regulations**

Dr. Cindy Jacobs (UW & ITHS) [[1:12:41](#)]

### **AI Regulation in Washington State (Presented by Dr. John Scott)**

- In 2021, Washington state passed [S.B. 5092](#), which establishes one-time funding in the 2021-2023 fiscal budget for the Washington Automated Decision-making Systems (ADS) Workgroup
  - This workgroup consists of representatives from across the state government and also includes AI academic experts and advocacy organizations that represent communities disproportionately harmed by AI bias.
  - As its final deliverable, the workgroup published policy recommendations and explored the impact of those recommendations in a case study of an existing AI system used by a state agency.
- Outside of this workgroup, there has been continued interest in AI regulation in Washington state. Several major companies located in Washington state have called for greater regulation of AI, including Microsoft, Google, and Amazon. There are also several bills on AI regulation that have been brought to the legislature:
  - [S.B. 5116](#): Establishing guidelines for government procurement and use of automated decision systems
  - [H.B. 2401](#): Concerning the use of AI in job applications
  - [H.B. 2644](#): Concerning AI-enabled profiling

### **Digital Health Definitions – FDA (Following Slides Presented by Dr. Cindy Jacobs)**

- Software as a Medical Device: Software intended for one or more medical uses that may run on different operating systems or in virtual environments. Software run on a hardware medical device is a SaMD when not part of the intended use of the hardware medical device. This can include standalone software that is intended to run on general-purpose computers or mobile

platforms (e.g., smartphone, tablet). **Software is not SaMD if it drives or controls the hardware medical device.**

- **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.
- One rapidly growing area of Artificial Intelligence is machine learning. 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.
  - FDA has a specific list of [cleared] Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices—total of 699 as of October 5, 2022 update.
- **Interoperability:** A device or product that can exchange and use information through an electronic interface with another medical/non-medical product, system, or device.
- SPS (“What”) and ACP (“How”)
  - **SaMD Pre-Specifications (SPS):** A SaMD manufacturer’s anticipated modifications to “performance” or “inputs,” or changes related to the “intended use” of AI/ML-based SaMD. These are the types of changes the manufacturer plans to achieve when the SaMD is in use. The SPS draws a “region of potential changes” around the initial specifications and labeling of the original device. This is "what" the manufacturer intends the algorithm to become as it learns.
  - **Algorithm Change Protocol (ACP):** Specific methods that a manufacturer has in place to achieve and appropriately control the risks of the anticipated types of modifications delineated in the SPS. The ACP is a step-by-step delineation of the data and procedures to be followed so that the modification achieves its goals, and the device remains safe and effective after the modification.
- **Novel Digital Health:** A device or product that includes new, unfamiliar, or unseen digital health technology never submitted, cleared, or approved by FDA. The technology could potentially be a de Novo, have a new intended use, or have different technological characteristics. This also includes digital health technology or topic areas that have no agreed upon or established definition by industry or FDA.
- Examples of novel digital health technologies include but are not limited to:
  - Virtual Reality
  - Gaming
  - Medical Body Area Network (MBAN) wearable or implanted wireless devices
- **RWD** (real world data): data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.
- **RWE** (real world evidence): clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD.
- Other assorted definitions

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- Advanced Analytics
- Cloud
- Wireless
- Cybersecurity
- Medical Device Data System
- Mobile Medical App

## Privacy/Security Issues r/t Digital Health Devices

- Is FDA's jurisdiction related to privacy and security the result of magical thinking?
- FDA has no express authority under HIPAA statutes or regulations
- FDA frames this issue as a device safety issue, over which it does have authority/jurisdiction
- “Patient harm is defined as physical injury or damage to the health of patients, including death. Cybersecurity exploits (e.g., loss of authenticity, availability, integrity, or confidentiality) of a device may pose a risk to health and may result in patient harm.”
- Device cybersecurity requires a multi-agency approach
  - FDA
  - NIST (National Institute of Standards and Technology)
  - Department of Homeland Security, Science and Technology
  - OCR (Enforcement—also enforces HIPAA)
  - FDA also works with other stakeholder organizations

## FDA Cybersecurity Materials

- In collaboration with MITRE (a company “established to advance national security in new ways and serve the public interest as an independent adviser”), the FDA developed the **Medical Device Cybersecurity Regional Incident Preparedness and Response Playbook**,\* a resource to help health care organizations prepare for cybersecurity incidents. The playbook focuses on preparedness and response for medical device cybersecurity issues that impact device functions.
- The Playbook was revised as of November 15, 2022
  - **Emphasizing the need to have a diverse team participating in cybersecurity preparedness and response exercises – including clinicians, health care technology management professionals, IT, emergency response, and risk management and facilities staff.**
- \*<https://www.mitre.org/news-insights/publication/medical-device-cybersecurity-regional-incident-preparedness-and-response>
- Highlighting considerations for widespread impacts and extended downtimes during cybersecurity incidents which benefit from the use of regional response models and partners.
- Adding a resource appendix making it easier to find tools, references, and other resources to help health care organizations prepare for and respond to medical device cybersecurity incidents (including ransomware).

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- A Playbook Quick Start Companion Guide is also available. The guide is a shorter version of the playbook that discusses preparedness and response activities health care organizations might want to start with as they are developing their medical device incident response program.
- October 7, 2022: FDA released a new video, “Tips for Clinicians - Keeping Your Patients’ Connected Medical Devices Safe” (<https://youtu.be/oxLbTPdtsLI>) to help clinicians discuss cybersecurity of connected medical devices with patients. These tips focus on communicating with patients and aim to increase clinician comfort in approaching this topic.
- Other available materials at FDA digital health website pages\*
  - Cybersecurity News and Updates
  - Mitigating Cybersecurity Risks
  - Cybersecurity Reports and White Papers
- \*<https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity>
- Cybersecurity Safety Communications and Other Alerts
- Reporting Cybersecurity Issues
- MOUs on Cybersecurity in Medical Devices
- Workshops and Webinars on Cybersecurity
- Other Collaborations on Cybersecurity
- FDA Cybersecurity New Releases

## Device Cybersecurity Guidance (Draft)

- **Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions**
- Updated 4/8/2022
- This draft guidance replaces the 2018 draft version (*which had a different title*) 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.
- The need for effective cybersecurity to ensure medical device functionality and safety has become more important with the increasing use of wireless, Internet-and-network- connected devices, portable media (e.g. USB or CD), and the frequent electronic exchange of medical device-related health information. In addition, cybersecurity threats to the healthcare sector have become more frequent, more severe, and more clinically impactful.
- Cybersecurity incidents have rendered medical devices and hospital networks inoperable, disrupting the delivery of patient care across healthcare facilities in the US and globally. Such cyberattacks and exploits can delay diagnoses and/or treatment and may lead to patient harm.
- This guidance is intended to provide recommendations to industry regarding cybersecurity device design, labeling, and the documentation that FDA recommends be included in premarket submissions for devices with cybersecurity risk. These recommendations can facilitate an efficient premarket review process and help ensure that marketed medical devices are sufficiently resilient to cybersecurity threats.

- Although FDA issued final guidance addressing premarket expectations in 2014 and a draft guidance in 2018,\* the rapidly evolving landscape, and the increased understanding of the threats and their potential mitigations, necessitates an updated approach.
  - \*FDA regularly replaces “final” guidances with new draft guidances
- This guidance applies to all types of devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) **whether or not they require a premarket submission**. Therefore, the information in this guidance should also be considered for understanding FDA’s recommendations for devices for which a premarket submission is not required (e.g., for 510(k)-exempt devices).
- The changes proposed since the 2014 guidance are intended to further emphasize the importance of ensuring that devices are designed securely, are designed to be capable of mitigating emerging cybersecurity risks throughout the TPLC, and to more clearly outline FDA’s recommendations for premarket submission information to address cybersecurity concerns.
- One way these TPLC considerations for devices can be achieved is through the implementation and adoption of a Secure Product Development Framework (SPDF). An SPDF is a set of processes that reduce the number and severity of vulnerabilities in products throughout the device lifecycle.
- The recommendations in this guidance also generally align with or expand upon the recommendations in the Pre-Market Considerations for Medical Device Cybersecurity section of the International Medical Device Regulators Forum final guidance “Principles and 110 Practices for Medical Device Cybersecurity,” issued March 2020
  - *(FDA has increasingly been aligning with IMDRF guidances and standards)*
- How does the revised draft compare with the 2018 draft?
  - Scope is much broader; applies to all medical devices, not just those requiring some type of approval process
    - Note, however, that the guidance does focus largely on requirements for pre-market submissions
  - “Cybersecurity Tiers” (Level 1 and 2 devices) are gone; all medical devices are subject to the same standards
- About the only recognizable specific content from the previous draft (in definitions):
  - Trustworthy Device – a medical device that: (1) is reasonably secure from cybersecurity intrusion and misuse; (2) provides a reasonable level of availability and reliability; (3) is reasonably suited to performing its intended functions; and (4) adheres to generally accepted security procedures to support correct operation.

#### **What does all this have to do with telemedicine practice?**

- The FDA’s mantra: **We do not regulate the practice of medicine**
  - Clinical practice liability for telemedicine use of SaMD, AI/ML, etc., would be in the malpractice arena, under state licensing laws, or related to HIPAA obligations (or state privacy law) as a covered entity

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- Be aware of which devices your telemedicine patients are using when you are incorporating device data into your telemedicine practice. Examples include
  - RPM devices directly communicating with the EHR or whose data are being organized into a dashboard communicating with the EHR
  - Patient uploads of their own diary data from devices
- Are these devices FDA-cleared (if required)?
- What do the devices' cybersecurity labeling include?
- How does your own clinical privacy/security setup comply with HIPAA regarding the transfer and storage of device data?
- Are you able to independently review device data in a clinical decision-making situation?
  - Particularly important to the FDA with respect to its regulation of AI/ML decision support systems

## Questions/Discussion:

- Many of these policies and regulations were made before the large language models came out (e.g. ChatGPT-4) – do you feel like the FDA would have to go back to the drawing board and change some of their policies or do they have enough of a foundation to account for some of these newer models?
  - There hasn't been any word/action on this yet. But based on how AI and computer assistive diagnosis have been treated, it is unlikely that the FDA will be successful on their ability to independently review the data
  - The FDA has been working with NIST and will continue to do so as the AI looks more like what's going on with ChatGPT-4
  - The FDA does have the ability to publish a regulation saying that they're going to retain jurisdiction on a certain type of software depending on the risks and see if this gets challenged
  - Most likely the FDA will stick with the same concepts
- Dr. John Scott emphasizes the importance of privacy and security since there have been a number of requests from clinicians asking to use an application to track patient information – these ended up being malware
  - He cautions those that are going to work with anything outside a third-party vendor, to make sure that they are in compliance with the HIPAA and FDA rules
  - Dr. John Scott highlights folks to remind their clinicians about this. If specific information is being put into a chat-like question, it is possible that this information can be identifiable because it gets released into the public

## Action Item

- If the Collaborative members have any further questions, reach out to Dr. Cindy Jacobs at [cajacobs@uw.edu](mailto:cajacobs@uw.edu).



## TeleBehavioral Health Summit

Dr. Bradford Felker (VA Puget Sound) [[1:39:01](#)]

- **What:** free two-day, CME-accredited virtual conference, focusing on today’s emerging topics in digital and TeleBehavioral health care – presented virtually by the Behavioral Health Institute at Harborview Medical Center in partnership with the Northwest Regional Telehealth Resource Center (NRTRC)
  - National subject matter experts & thought leaders
  - TeleBH challenges and innovations
  - PN-25 TeleBH track
  - New “digital landscape” accelerated by PHE
  - Policy issues as PHE ends May 11, 2023
- **When:** Tuesday/Wednesday, May 9 & 10, 10:00 am – 3:30 pm (PDT)
- **How & Cost:** Virtual conference and free to attend. Register at <https://bhinstitute.uw.edu/events/tbh-summit/>
- **Who:** Anyone providing/leading services for people living with mental health and substance use issues
- **Continuing Education:**
  - Certificate of Attendance provided at no cost
  - Continuing Medical Education credits: max 8 credits for \$25
  - Accreditation with Commendation: The University of Washington School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians
  - Credit Designation: The University of Washington School of Medicine designates this Live Activity for a maximum of 8 *AMA PRA Category 1 credits*<sup>™</sup>. Physicians should claim only the credit commensurate with the extent of their participation in the activity.
- Over 1100 folks have already registered for the conference from all over the country
- Dr. Felker walks through a brief overview of the agenda and speaker line-up where national speakers have been invited to this conference, including Dr. Peter Yellowlees, Dr. Jay Shore, etc.

### Questions/Discussion:

- Dr. John Scott shares that the speaker line-up includes very well-known folks where if anyone reads the seminal papers, their names are listed.
- Nicki Perisho (NRTRC) adds the link to register for the TeleBehavioral Health Summit on May 9 and 10: <https://bhinstitute.uw.edu/events/tbh-summit/>
- Is the conference free?
  - Yes

### Action Items

- If the Collaborative members have any further questions, reach out to Dr. Bradford Felker at [Bradford.Felker@va.gov](mailto:Bradford.Felker@va.gov).

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## Wrap Up/Public Comment Period

[1:46:23]

- Jim Freeburg (Patient Coalition of Washington) shares that they are the state's leading patient group to have one voice for better health care. They have 17 members who represent a wide range of chronic conditions including mental health (e.g. ALS Association, National Multiple Sclerosis Society, etc.). The coalition exists to advocate for improved state policy – their members often work in multiple states and so, they serve as a great resource to understand what's happening in other states.
  - The coalition also exists because they've seen a huge gap in the representation of patients and health care policy discussions
  - They would like to request a formal patient representative on the Collaborative as allowed in our authorizing statute.
  - He recommends one of their members to be the patient representative on the Collaborative, Clark Hanson, the Managing Director of the Advocacy for the ALS Association
    - The ALS Association has had a long-standing interest in telemedicine policy
  - The 4 legislators on the Collaborative are the authorizing body and will connect with them regarding this request
- Next meeting: Monday, July 17, 2023 at 10:00 am – 12:00 pm
- Meeting materials, including presentation slides and recording, will be posted on the [Collaborative's website](#) and sent out via the newsletter

### **Action Items**

- Collaborative members to share agenda topics for future Collaborative meetings and email them to Dr. Scott / Mrs. Dinh Hsieh
- Dr. Scott to connect with the 4 legislators on the Collaborative regarding the request for a patient representative on the Collaborative

### **Tentative Next Meeting Items:**

Uniform Telehealth Bill by Senator Cleveland

Genetic Counseling via Telemedicine

House Bill 1196: Study of the Cost Impact of Audio-Only Telemedicine Updates

Overview of Medicaid Telehealth policies

Meeting adjourned at 11:51 am

Next meeting: July 17, 2023: 10 am-12 pm

Via Zoom.