



Opportunities and Challenges for UK and EU businesses in the U.S. Digital Health Sector

5 October 2022

Agenda

- Introductions & Welcome
- Overview of the U.S. healthcare reimbursement and payment ecosystem
 - Medicare
 - Medicaid
 - Private insurance
- Overview of Key Grant/Partnership Opportunities
 - Grant/Partnership Opportunities
 - Federal Communications Commission
 - National Telecommunications and Information Administration
- Open Discussion/Questions
- Next Steps
- Adjourn



About CHI

- The CHI is a not-for-profit multi-stakeholder consensus advocacy effort to advance uptake of digital health tools widely
 - Reimbursement & payment
 - Privacy & security
 - Efficacy & quality assurance
 - Health equity
 - Value-based care
 - Artificial intelligence/machine learning
- Policy advocate before US government, UK government, European Commission, etc.
- Active in key private-sector initiatives (e.g., AMA Digital Medicine Payment Advisory Group)
- For more: www.connectedhi.com



Overview of the U.S. healthcare reimbursement and payment ecosystem

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Coding – Background

- The Healthcare Common Procedure Coding System (HCPCS) is a collection of standardized codes that represent medical procedures, supplies, products and services. The codes are used to facilitate the processing of health insurance claims by Medicare and other insurers.
 - Level I (CPT® codes)
 - Level II (CMS-created, identify products, supplies, and services not included in CPT)
- The Current Procedural Terminology (CPT®), maintained and updated by the CPT® Editorial Panel, offers doctors and health care professionals a uniform language for coding medical services and procedures to streamline reporting, increase accuracy and efficiency.
 - Category I (correspond to a procedure or service)
 - Category II (supplemental codes used for performance measurement)
 - Category III (temporary codes for new and developing technology, procedures and services)



- Safetynet health insurance coverage for adults age 65 and older and some people with long-term disabilities and end-stage renal disease
 - ~65 million beneficiaries
- Parts
 - Part A (hospital insurance)
 - Part B (medical insurance)
 - Part C (Medicare Advantage) [~45% of all beneficiaries]
 - Part D (drug coverage)

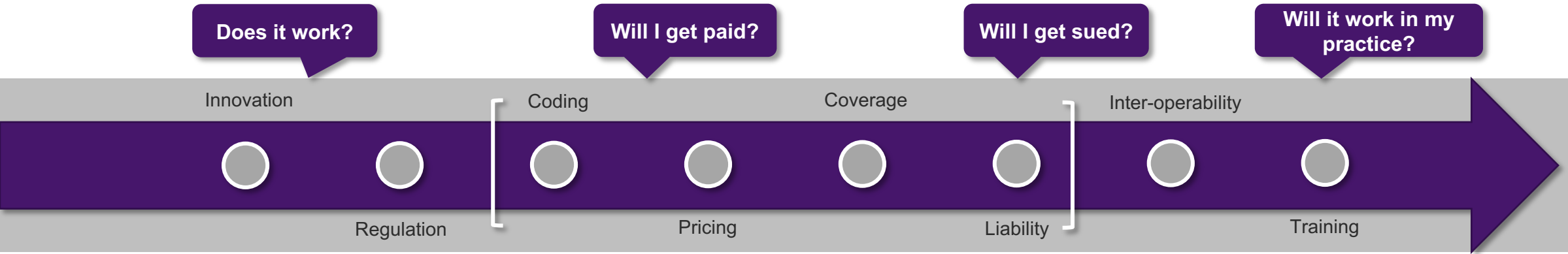
Medicare Basics

What Digital Health Technologies Does Medicare Address?

(in the Medicare Physician Fee Schedule – influencing other payment rules)

- Medicare Telehealth Services
- Communications Technology Based Services (CBTS)
- Remote Physiologic Monitoring (RPM)
- Remote Therapeutic Monitoring (RTM)
- Artificial Intelligence
- Quality Payment Program (MIPS/APMs)

The AMA-Convened Digital Medicine Payment Advisory Group (DMPAG)



Aggregate evidence base

Address gaps in coding

Propagate widespread coverage

- ✔ Engaged the CPT® Editorial Panel by proposing new CPT codes for digital medicine services such as Remote Physiologic and Therapeutic Monitoring, Internet Consultation, eVisits, and Point-of-care Diabetic Retinopathy
- ✔ Gain broader coverage of remote monitoring and augmented intelligence services with payers like CMS
- ✔ DMPAG created use cases and consolidated evidence from hundreds of studies

15 nationally recognized advisors

Medicare: Remote Physiologic Monitoring Payments

Code	Descriptor	2021	2022
99453	Initial set-up & patient education	\$19.19	\$19.03
99454	Device supply, daily recordings, transmissions, each 30 days	\$63.16	\$55.72
99457	Treatment management by clinician, first 20 mins/month	\$50.94	\$50.18
99458	Treatment management by clinician, each additional 20 mins/month	\$41.17	\$40.84

Source: CMS CY2021 Physician Fee Schedule final rule, <https://www.cms.gov/files/document/12120-pfs-final-rule.pdf>

Medicare: Remote Therapeutic Monitoring Payments

Code	Descriptor	2022
98975	Initial set-up & patient education	\$19.38
98976	Device supply, daily recordings, transmissions, each 30 days - respiratory	\$55.72
98977	Device supply, daily recordings, transmissions, each 30 days - musculoskeletal	\$55.72
98980	Treatment management by clinician, first 20 mins/month	\$50.18
98981	Treatment management by clinician, each additional 20 mins/month	\$40.84

Source: CMS CY2022 Physician Fee Schedule final rule, <https://public-inspection.federalregister.gov/2021-23972.pdf>

Artificial Intelligence

Key developments in coding include:

- 2021 CMS activation and payment for use of AI in supporting diabetic retinopathy clinical decisions (CPT code 92229, paid on average at \$45.69)
- Wide-ranging request for information in CY2022 Medicare Physician Fee Schedule
- Finalization of CPT Editorial Panel's Appendix S (<https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures>)

Sources:

- CMS CY2021 Physician Fee Schedule final rule, <https://www.cms.gov/files/document/12120-pfs-final-rule.pdf>
- CMS CY2022 Physician Fee Schedule final rule, <https://public-inspection.federalregister.gov/2021-23972.pdf>
- CPT Appendix S, <https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures>

Transitioning to Value-Based Care

- **Quality Payment Program**
 - Merit-based Incentive Payment System (MIPS)
 - Alternative Payment Models (APMs)
- **Accountable Care Organizations**
 - Medicare Shared Savings Program



Sources:

- <https://app.cms.gov/>
- <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO>

Other Federal Programs

Home Health
Prospective
Payment System

Outpatient
Prospective
Payment System

Medicare
Advantage

Durable Medical
Equipment

TRICARE/Veterans
Administration

Indian Health
Service

States

- State government-administered safety net programs for, generally, low-income individuals and those with disabilities
 - Medicaid covers ~ 18% of Americans
 - CHIP covers ~10 million American children
 - Affordable Care Act expansion (additional ~20 million enrollees)
- Private health insurance rules
- More information on state rules for digital health coverage: <https://www.cchpca.org/>



Private Insurance

- Generally, employers contract with private health plans to administer benefits, covering workers and dependents
 - Both employers and employees typically contribute to premiums
- 2/3 of Americans have private insurance as primary insurer (55% employer-sponsored)
- Private health insurance spend = 1/3 of total U.S. healthcare expenditures
- More than 1/3 of Medicare beneficiaries opted to receive coverage through private Medicare-Advantage plans
- There is no nationally defined benefit package, however the ACA required private plans to cover 10 “essential health benefits”
- Benefits vary from plan to plan, giving the employer some say in what services are covered





Grant/Partnership Opportunities

Start With Research

- What type of opportunities are you seeking? Research and filter to find the best-fit.
 - Government
 - Public orgs
 - Private

- Grants, partnerships, funding, & contracts
 - State / Local
 - Federal - HHS, NIH, Medicare, FCC
 - International - USAID

US Government Funding

Public Orgs

- Grants, partnerships, funding, & contracts
 - Healthcare Providers (Hospitals)
 - Nonprofits / Research Groups - AMA, Alzheimer's Association, American Cancer Society
 - Universities - Harvard Medical, John Hopkins
 - Foundations - Gates Foundation, Robert Wood Johnson

Private Orgs

- Grants, partnerships, funding, & contracts
 - Insurance companies
 - Pharma
 - Medical Devices

RFPs and Grant Writing

- Paperwork submissions, proposals, due diligence
 - Grant submission forms
 - Long business development cycles
 - Impersonal process

Setting Up for Success

- You must set yourself apart from the competition.
 - Demonstrate your solution's value
 - Show your expertise and ability to execute
 - Foreign vs U.S. entities
 - De-risk the decision-making process
 - Meet budget constraints

Examples

NIH Grants

Phrma
Foundation

Pfizer Grants

HHS Grants &
Contracts

Grants.gov

SAMSA Grants

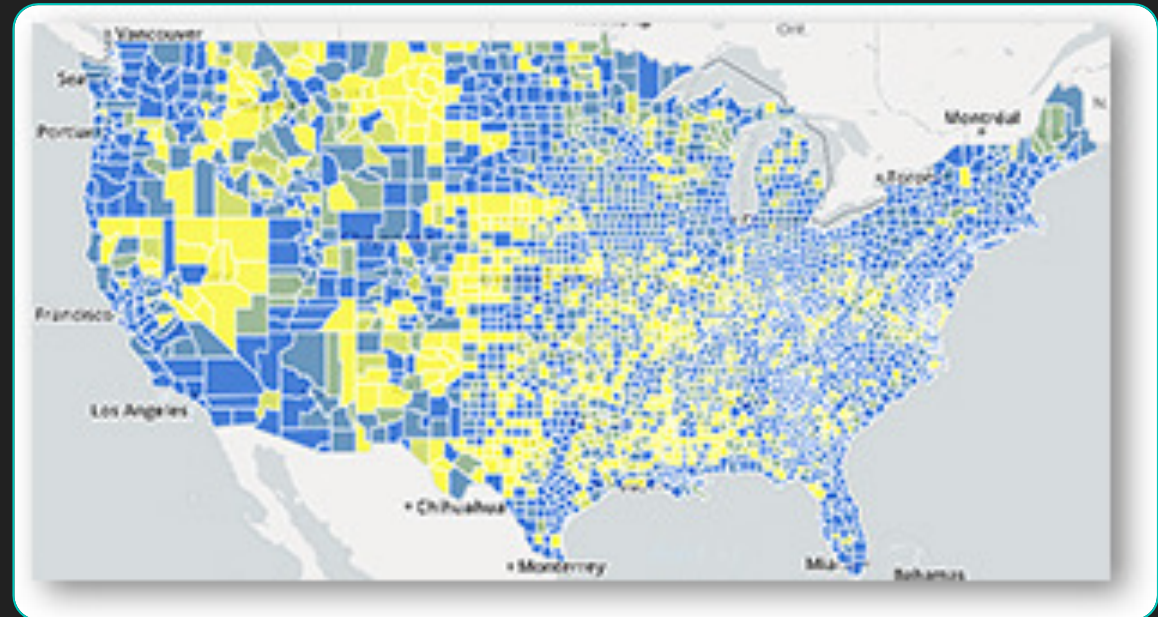
Agency for
Healthcare
Research and
Quality

American
Association of
Cancer
Research

American
Cancer Society

Federal Communications Commission (FCC)

- Universal Service Fund (Rural Health Care Program)
- Connected Care Pilot Program
- COVID-19 Telehealth Program



Sources:

- FCC RHCP: <https://www.fcc.gov/general/rural-health-care-program>
- FCC Connected Care Pilot Program: <https://www.fcc.gov/wireline-competition/telecommunications-access-policy-division/connected-care-pilot-program>
- FCC COVID-19 Telehealth Program: <https://www.fcc.gov/covid-19-telehealth-program-invoices-reimbursements>

Image credit: FCC

National Telecommunications and Information Administration (NTIA)

- Infrastructure Investment and Jobs Act (IIJA) allocates \$48.2 billion for broadband/equity projects, to be administered by NTIA
 - Broadband Equity, Access, and Deployment (BEAD) Program: \$42.45 billion
 - Enabling Middle Mile Broadband Infrastructure Program: \$1 billion
 - Tribal Broadband Connectivity Program: \$2 billion
 - Digital Equity Act Programs: \$2.75 billion
 - State Digital Equity Planning Grant Program: \$60 million
- Grants to states, who will run processes to awards funds to applicants



Source: <https://broadbandusa.ntia.doc.gov/news/latest-news/ntias-role-implementing-broadband-provisions> Image credit: FCC
[2021-infrastructure-investment-and](#)

2022 and Beyond



Thank You!

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Medicare's Initial Support for Remote Monitoring

Code 99091 unbundled/activated by CMS

99091 > Collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days

- Assigned coverage and payment by CMS through 2018 Final Physician Fee Schedule Rule (posted November 2017)
- Went into effect on January 1, 2018

Medicare: Remote Physiologic Monitoring

CPT Codes 99453, 99454, 99457 in effect Jan. 1, 2019

Remote Physiologic Monitoring (PE Only)

- 99453 > 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
 - Once per episode of use (i.e., one time set-up fee)
- 99454 > device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days
 - Once per 30 days (do not report if less than 16 days)

Medicare: Remote Physiologic Monitoring-Treatment Management Services

CPT Codes 99453, 99454, 99457 in effect Jan. 1, 2019; CPT Code 99458 in effect Jan. 1, 2020

Remote Physiologic Monitoring/Treatment Management Services (Work)

- 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; initial 20 minutes
- 99458 > 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; additional 20 minutes

Source: CMS CY2021 Physician Fee Schedule final rule, <https://www.cms.gov/files/document/12120-pfs-final-rule.pdf>

Medicare: Remote Physiologic Monitoring- Treatment Management Services & Other Care Management Services

Report in Conjunction with other Care Management Services

CPT Codes 99457, 99458 may be reported during the same service period as:

- Chronic care management services (99437, 99439, 99487, 99489, 99490, 99491)
- Principal care management services (99424, 99425, 99426, 99427)
- Transitional care management services (99495, 99496)
- Behavioral health integration services (99484, 99492, 99493, 99494)

Medicare: Remote Therapeutic Monitoring (2022)

Four PE Only Codes: 98975, 98976, 98977 (not part of 2022 Fee Schedule = 989X6)

Remote Therapeutic Monitoring (PE)

- **98975** > 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** > device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days
- **98977** > device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days
- **989X6** (as of 1/1/2023 – TBD on coverage and/or payment) > device(s) supply with daily recording(s) or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days

Source: CMS CY2022 Physician Fee Schedule final rule, <https://public-inspection.federalregister.gov/2021-23972.pdf>

Medicare: Remote Therapeutic Monitoring- Treatment Management Services

Two Work Codes = 98980, 98981 (in effect January 1, 2022)

Remote Therapeutic Monitoring / Treatment Management Services (Work)

- 98980 > 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 > 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

Source: CMS CY2022 Physician Fee Schedule final rule, <https://public-inspection.federalregister.gov/2021-23972.pdf>