Presentation to American Congress of Rehabilitation Medicine's Technology SIG – Pandemic Task Force

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Connected Health Initiative

Agenda

- About the Connected Health Initiative (CHI)
- Payment/Reimbursement
  - Physician Fee Schedule (PFS)
  - Home Health Prospective Payment System (HHPPS)
  - Medicare Advantage
  - Quality Payment Program (QPP)
- Infrastructure and Connectivity
- Privacy/Security
- Health Data Interoperability
- FDA Regulation of Digital Health
- Healthcare & AI
- COVID-19 Policy Changes
- Discussion/Questions

About CHI

- The CHI is a not-for-profit multi-stakeholder consensus advocacy effort to advance uptake of digital health tools widely
- Intersection of medical/health industry and technology innovators
- Advocate before Capitol Hill, US agencies, European Commission, etc.
- Active in key private-sector initiatives (AMA Digital Medicine Payment Advisory Group, Xcertia, etc)

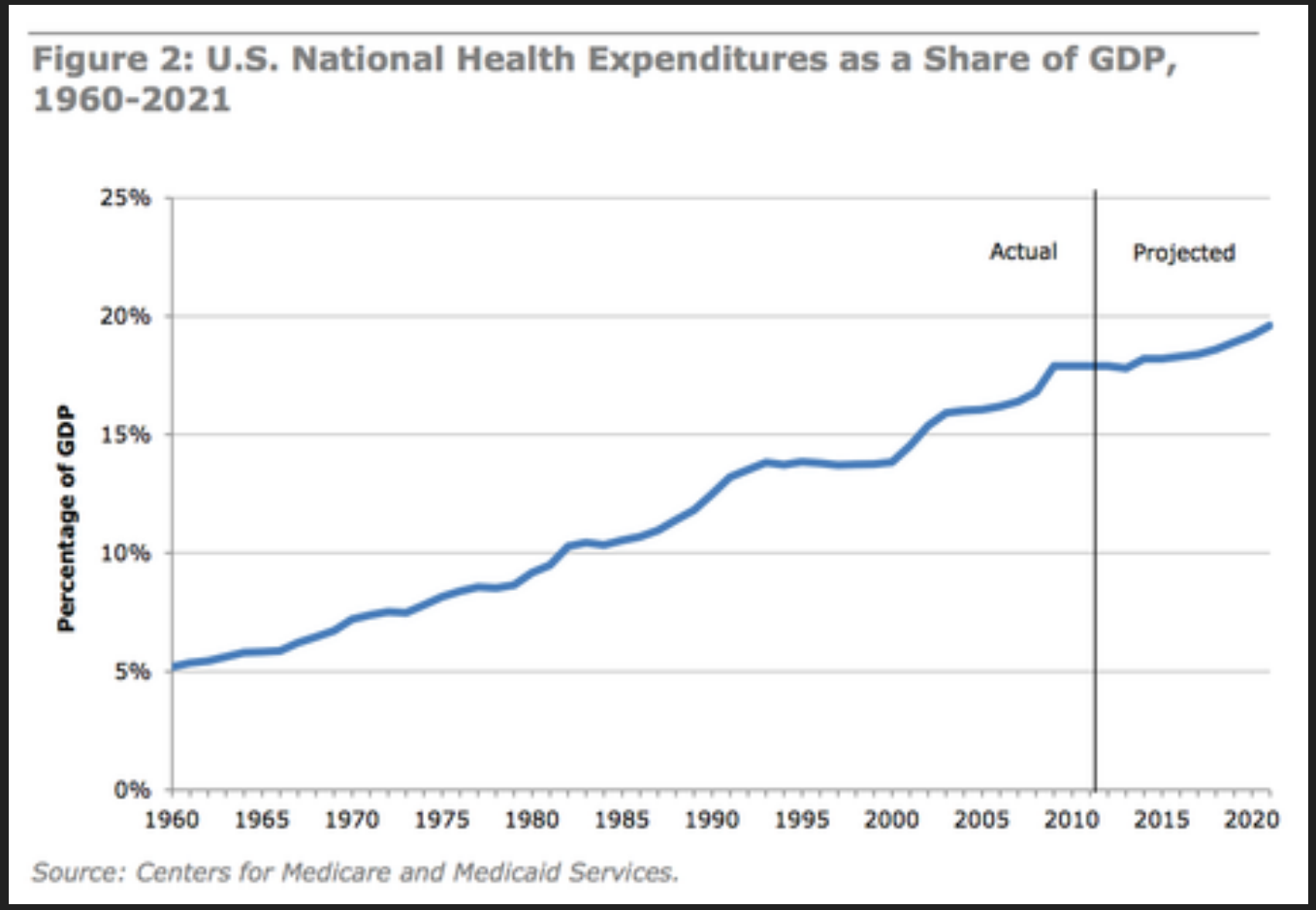
About CHI

ConnectedHealth

Growing Needs (and Costs)

- 133 million+ Americans suffer from chronic conditions such as diabetes, chronic obstructive pulmonary disease, and mental illness (~171 million by 2030)
- U.S. health care spending to reach 20% of the entire U.S. economy 2025

Growing Needs (and Costs)



Connected Health Tech in 21st Century Health Care Systems

- Strong (and growing) body of evidence shows that connected health tech [see https://bit.ly/2MblRou]:
  - Improves patient care
  - Reduces hospitalizations
  - Helps avoid complications
  - Improves patient engagement
  - Reduces health care costs
- Driving Internet of Things marketplace (valued at over $250B in the U.S. alone)
- Job creation

Medicare Reimbursement — Background and Status Quo

- "Telehealth" vs. "store-and-forward"
- 1834(m) & the historical treatment of "Medicare Telehealth Services"
  - Telehealth Services List
- Historical treatment of remote monitoring
  - Remote monitoring is <u>not</u> telehealth subject to 1834(m) restrictions
- Legislative efforts to address:
  - CONNECT for Health Act
  - Bipartisan Budget Act (Medicare Telestroke, ESRD, MA, ACOs) ***[PASSED]***
  - SUPPORT for Patient and Communities Act

CY2018-19 PFS' & Digital Health

- CPT code 99091 – Collection and interpretation of physiologic data to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) 30 min minimum each 30 days.
- HCPCS code G2012 – Brief communication technology-based service (e.g., virtual check-in).
- HCPCS code G2010 – Remote evaluation of pre-recorded patient information.
- CPT codes 99453, 99454, and 99457 – Chronic care remote physiologic monitoring
- CPT codes 99446, 99447, 99449, 99451, 99452 – Interprofessional internet consultation.
- Updates to Medicare Telehealth Services List

CY2020 PFS & Digital Health

- General Supervision for "incident to" services provided under CPT Codes 99457 and 99458
- Reimbursement for additional time spent on Remote Patient Monitoring (CPT Code 99458)
- Reimbursement for Online Digital Evaluation Services ("e-Visits")
- One-time advance beneficiary consent for "a number of communication technology-based services" including Virtual Check-Ins, Remote Evaluation of Images, and Interprofessional Internet Consultations
- Changes to CCM & TCM
- Creation of Personal Care Management (PCM) services
- Medicare Telehealth Services list

PFS: CPT 99453, 99454, 99457, and 994X0

- Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate)
  - CPT 99453 – initial; set-up and patient education on use of equipment
  - CPT 99454 – initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days
  - CPT 99457 – treatment management services
    - 20 minutes or more of clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month
  - CPT 99458 – subsequent 20-minute intervals of RPM services provided by clinical staff, physician, or QHCP spent above and beyond the initial 20 minutes in a calendar month indicated for CPT Code 99457
- CMS to provide additional guidance regarding these codes

PFS: CPT 99453, 99454, 99457, and 99458

Code	Descriptor	2019 (Final)	2020 (Proposed)
99453	Initial set-up	$19.46	$18.77
99454	Device supply, daily recordings, each 30 days	$64.15	$62.07
99091	Clinician interpretation of data, 30 mins, each 30 days	$58.38	$58.83
99457	Treatment management by clinician, first 20 mins/month	$51.54	$51.25
99458	Treatment management by clinician, each additional 20 mins		$36.09

Home Health Prospective Payment System & RPM

- Home health agencies (HHAs) are public, nonprofit or proprietary agencies that provide skilled nursing services and at least one of the following other therapeutic services: physical therapy, speech language pathology, or occupational therapy, medical social services, or home health aide services in a place of residence used as a patient's home.
- The HHPPS provides HHAs with payment under a retrospective reimbursement system for all Medicare-covered home health services furnished under a plan of care (POC) paid on a reasonable cost basis.
- In 2016, about 3.4 million Medicare beneficiaries received care, and the program spent about $18.1 billion on home health care services.

Medicare Advantage

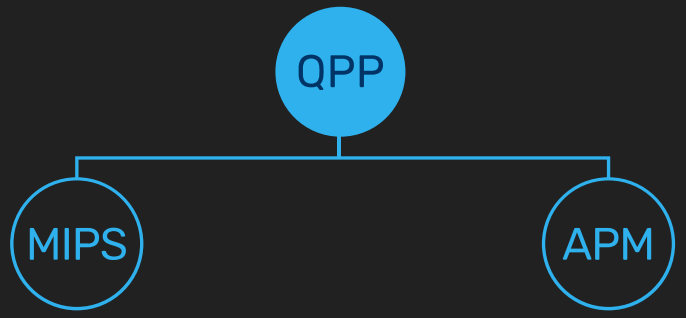
- Medicare Advantage Organizations may also provide enrollees access to Medicare Part B services via telehealth in any geographic area and from a variety of places, including beneficiaries' homes.
- As of CY2019, RPM's eligibility for inclusion as a basic benefit has been confirmed.

Quality Payment Program

- Until 2015, payment increases for Medicare services were set by the Sustainable Growth Rate (SGR) law which capped spending increases according to the growth in the Medicare population. SGR had to be passed by Congress annually.
- Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) repealed SGR and created the Quality Payment Program (QPP) to "reward high value, high quality Medicare clinicians with payment increases — while at the same time reducing payments to those clinicians who aren't meeting performance standards."

Quality Payment Program

- Clinicians have two tracks to choose from in the Quality Payment Program based on their practice size, specialty, location, or patient population:
  - Merit-based Incentive Payment System (MIPS)
  - Advanced Alternative Payment Models
- QPP started on January 1, 2017
- More information: https://qpp.cms.gov/



Quality Payment Program

Merit-based Incentive Payment System (MIPS)

- Performance measured through the data clinicians report:
  - Quality
  - Improvement Activities
  - Promoting Interoperability (formerly Advancing Care Information)

- MIPS designed to update and consolidate previous programs, including Medicare Electronic Health Records (EHR) Incentive Program for Eligible Clinicians, Physician Quality Reporting System (PQRS), and the Value-Based Payment Modifier (VBM).

Quality Payment Program — Key Policies in Place Today

- Improvement Activities (IA) notables:
  - “Engage Patients and Families *(using PGHD)* to Guide Improvement in the System of Care” is classified as a "high-weighted" activity
  - “Use of CEHRT to Capture Patient Reported Outcomes” remains a "medium-weighted" activity
- Performing Interoperability (PI) measures
  - 10% Bonus for using CEHRT to complete at least one IA

Quality Payment Program — Key Policies in Place Today

- MIPS
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  - Performing Interoperability (PI) measures
    - 10% Bonus for using CEHRT to complete at least one IA
- An Alternative Payment Model (APM) is a payment approach that gives added incentive payments to provide high-quality and cost-efficient care
  - Approved by both the Physician-Focused Payment Model Technical Advisory Committee (PTAC) & HHS
  - APMs can apply to a specific clinical condition, a care episode, or a population
  - <u>Remaining challenges:</u>
    - Rule text on Alternative Payment Models (APMs) still omits discussion of telehealth/remote monitoring
    - Lack of development of QPP APMs through PTAC & HHS

Quality Payment Program — CY2020

- Revisions to Quality Measures that would add in telehealth encounters to be included as eligible encounters, which include:
  - D.4. Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD);
  - D.10. Adult Major Depressive Disorder (MDD): Suicide Risk Assessment;
  - D.31. Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention;
  - D.40. Initiation and Engagement of Alcohol and Other Drug Dependence Treatment; and
  - D.53. Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment
- Request for Information regarding PI category and how best to prioritize the advanced use of CEHRT functionalities by moving away from paper-based processes and empowering individual beneficiaries to manage their health goals
- Continued omission of telehealth/RPM discussion in APM rules

Infrastructure and Connectivity

- Broadband deployment
  - Federal Communications Commission (FCC) Universal Service Fund
  - US Dept of Agriculture Rural Utility Service
- Wireless capacity/spectrum
- State/local infrastructure deployment policies

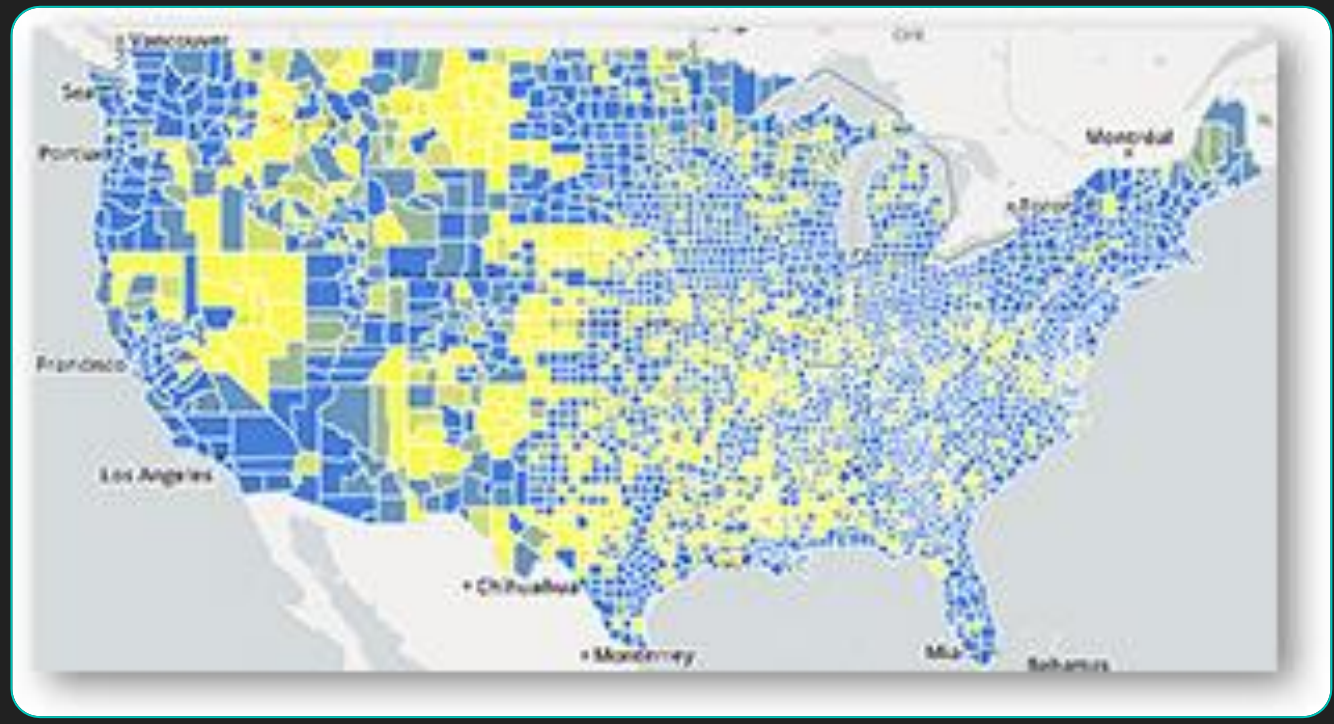


Image credit: FCC

Privacy/Security

- Health Insurance Portability and Accountability Act (HIPAA)
  - Reform efforts to promote connected care continuum
- General privacy frameworks & their impact on the health sector
  - States (CCPA, etc.) and locals
  - EU General Data Protection Regulation
  - US federal privacy framework efforts (Congress)
- Public-private partnerships
  - E.g., Health Sector Coordinating Council (HSCC)

Health Data Interoperability

- Long-standing efforts to address health data interoperability challenges
- New vehicles:
  - ONC information blocking rule
  - CMS interoperability rule
  - Trusted Exchange Framework and Common Agreement (TEFCA)
  - United States Core Data Initiative (USCDI)

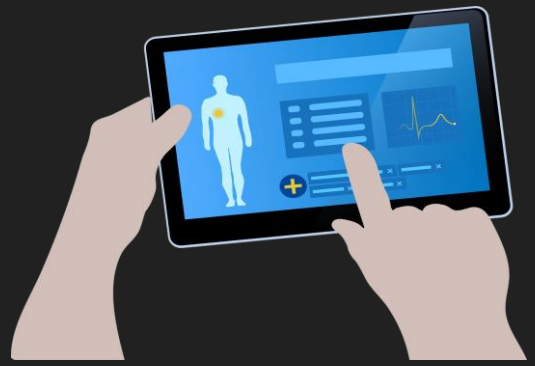
FDA Regulation of Digital Health

- Software Pre-Certification Program
- FDA Guidance
  - Software as a Medical Device (SaMD)
  - Clinical Decision Support
  - Cybersecurity Pre- and Post-Market Submission
  - Artificial Intelligence

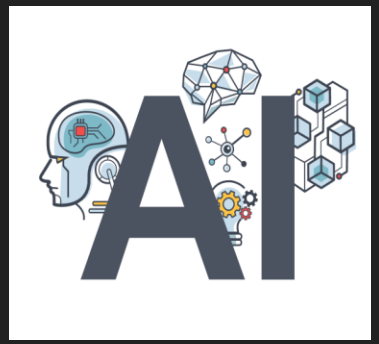
Healthcare & AI

- CHI convened a Task Force in mid-2018 to examine key issues within the health AI space, to advance understanding across the health community, and to seek cross-community consensus on the path forward for advancing the uptake of AI-driven innovations across care settings.
- Leverage good work of pre-existing efforts by groups such as the Partnership for AI, Xavier University, American Medical Association, etc.

Policy Principles



Why Does Health Care Need AI?



Key Terminology for AI in Health

COVID-19 Policy Changes

- Medicare Telehealth Services Expansion – 1135 Waiver
- Virtual Check-ins
- E-Visits
- MA
- PACE Orgs
- Suspended QPP Reporting
- HIPAA
- E-Prescribing
- FDA
- FCC

Further Barriers to COVID-19 & Digital Health

- Copay requirements
- Anti-Kickback Statute
- Scope of "Eligible Practitioner"
- Interstate Licensure
- Prior Authorization
- HIPAA
- Etc.

Questions

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