

REMOTE PATIENT MONITORING & DIGITAL HEALTH

Friday, November 17, 2023

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TODAY'S OBJECTIVES



- ◆ Overview of digital health, compliance risks and enforcement environment
- ◆ Understand RPM/RTM and structure of arrangements
- ◆ Discussion of compliance/enforcement risks of RPM/RTM

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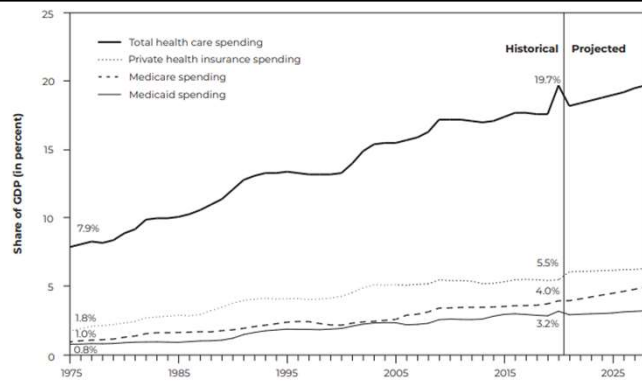
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OVERVIEW OF DIGITAL HEALTH

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HEALTHCARE SPENDING AS PERCENTAGE OF GDP CONTINUES TO GROW



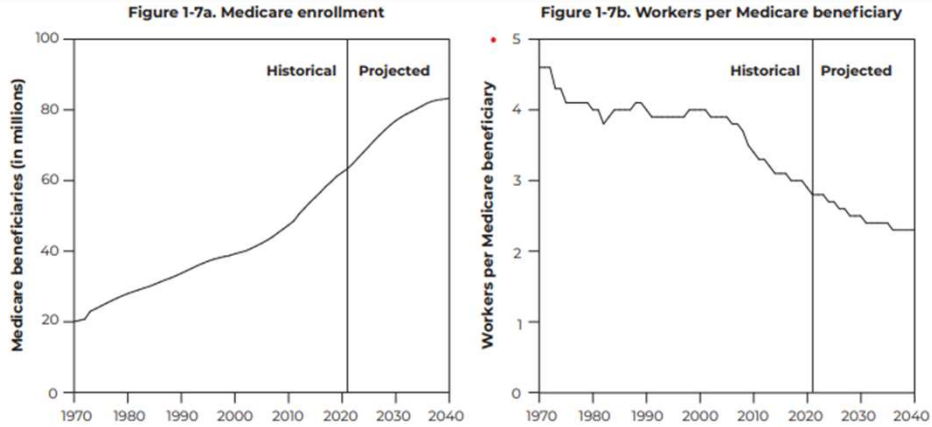
Note: GDP (gross domestic product). Spending projections in this graph are based on data released in March 2020 and do not reflect the impact of the coronavirus pandemic; historical spending levels in this graph are based on data released in December 2021 and do reflect the pandemic. First projected year in graph is 2021. Percentages labeled on graph are for 1975 and 2020. Beginning in 2014, private health insurance spending includes federal subsidies for both premiums and cost sharing for the health insurance marketplaces created by the Affordable Care Act of 2010. Health care spending also includes the following expenditures (not shown): out-of-pocket spending; spending by other health insurance programs (the Children's Health Insurance Program, the Department of Veterans Affairs, and the Department of Defense); and other third-party payers and programs and public health activity (including Indian Health Service; Substance Abuse and Mental Health Services Administration; maternal and child health; school health; workers' compensation; worksite health care; vocational rehabilitation; other federal, state, and local programs; other private revenues; and general assistance).

Source: MedPAC analysis of CMS's National Health Expenditure Data (projected data released in March 2020 and historical data released in December 2021).

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MEDICARE ENROLLMENT RISES & WORKERS DECLINE



Note: "Beneficiaries" referenced in these graphs are beneficiaries enrolled in Medicare Part A (including beneficiaries in Medicare Advantage). Part A is financed by Medicare's Hospital Insurance Trust Fund.

Source: 2021 annual report of the Boards of Trustees of the Medicare trust funds.

DIGITAL HEALTH - DEFINED

Digital health **connects and empowers people** and populations to **manage health and wellness**, augmented by accessible and supportive provider teams working within **flexible, integrated, interoperable, and digitally enabled care environments** that strategically **leverage digital tools, technologies, and services to transform care delivery**

Source: Health Information Management Systems Society (HIMSS)



WHAT IS DIGITAL HEALTH?



◆ Broad category of services:

- Mobile health and wellness apps
- Health information technology
- Clinical decision-making support software (AI, machine learning)
- Computing platforms
- Wearable devices
- Telemedicine
- Online health communities

Sources: <https://cms.gov/files/document/telehealth-toolkit-providers.pdf>;
<https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health>

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KEY PLAYERS IN DIGITAL HEALTH

Government

- Helping to pave the way for digital health
- Creating partnerships focused on accelerating digital health technologies

Payors

- Utilize digital health to increase member engagement, lower medical costs
- Investors/partners in DH

Providers

- Striving to be “digital front door” for patients
- Leverage digital health to pursue value-based care goals

Start-up Firms

- Driving forces for digital health innovations
- Try to find opportunities to collaborate with health care leaders

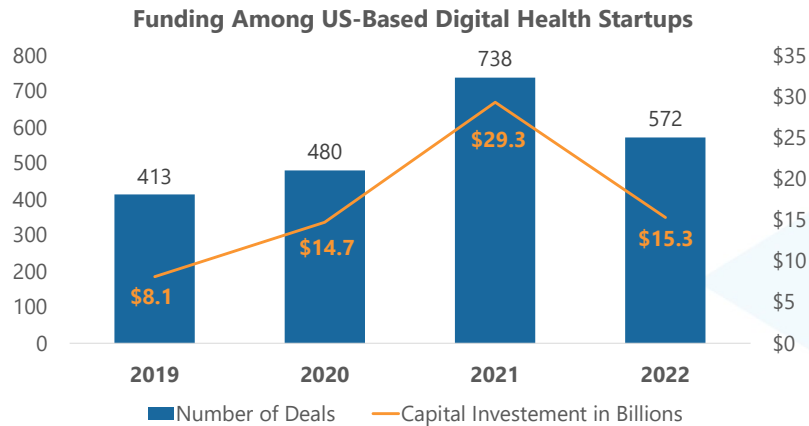
Big Tech

- Driving forces for digital health innovations
- Offers strengths in consumer engagement and analytics

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DIGITAL HEALTH INVESTMENT



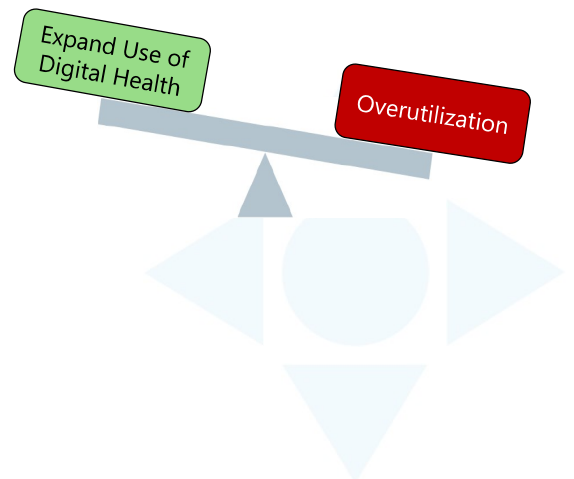
Source: Kyle Bryant, Madelyn Knowles, and Adriana Krasniansky, "2022 year-end Digital Health Funding", *RockHealth.org*, January 9, 2023

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BALANCING ACT

- ◆ Digital health and other disruptive technologies hold promise of improving patient care ...but also present legal/compliance risks
- ◆ Many companies pushing digital health and other innovations are not traditional healthcare companies (e.g., startups, technology companies, PE-backed companies)
 - Tend to be less sensitive to healthcare regulatory and enforcement environment
 - Business practices that are commonplace in other industries may violate healthcare fraud & abuse laws



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BENEFITS OF DIGITAL HEALTH

- ◆ Drive patient engagement
- ◆ Improve care coordination
- ◆ Support and management for chronic conditions
- ◆ Improve adherence to treatment plans
- ◆ Extend access to care beyond normal hours
- ◆ Reduce travel burdens
- ◆ Overcome provider shortages/underserved populations
- ◆ Protect vulnerable populations/prevent spread of diseases



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RISKS OF DIGITAL HEALTH

- ◆ Traditional fraud & abuse risks
 - Additional Cost
 - Overutilization
 - Quality of Care
 - Access to Care
 - Patients' Freedom of Choice
 - Competition
 - Exercise of Professional Judgment



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RISKS OF DIGITAL HEALTH

◆ Billing risks

- Upcoding time and/or complexity
- Misrepresenting service provided
- Billing for services not rendered
- Billing for services not provided effectively
- Billing for medically unnecessary services
- Billing for services by providers who are not appropriately licensed or not licensed in the appropriate jurisdiction



◆ Privacy risks

◆ Security risks

◆ FDA – patient safety risks

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TELEHEALTH'S PANDEMIC GROWTH STORY

- ◆ During the early months of the pandemic, CMS increased types of services that beneficiaries could access via telehealth
 - Medicare telehealth visits increased 63-fold, from approximately 840,000 in 2019 to 52.7 million in 2020
 - Medicare paid over \$5.1 billion in fee-for-service claims for telehealth services during first year of pandemic
- ◆ HIPAA enforcement discretion for telehealth during pandemic
- ◆ State regulatory flexibility during pandemic

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TELEHEALTH'S POST-PANDEMIC STORY



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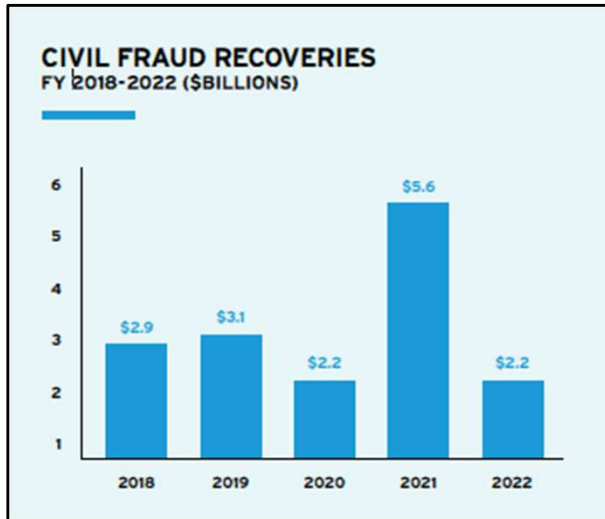
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ENFORCEMENT LANDSCAPE

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ENFORCEMENT OVERVIEW

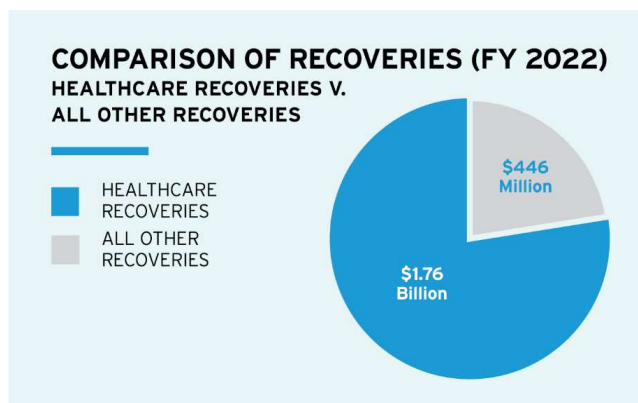


- ◆ \$2.2 billion total recoveries in FY2022
- ◆ FY2021 was skewed by \$3.2 billion in opioid settlements, including \$2.8 billion from Purdue Pharma
- ◆ 2nd highest number of settlements in history

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HEALTHCARE ENFORCEMENT



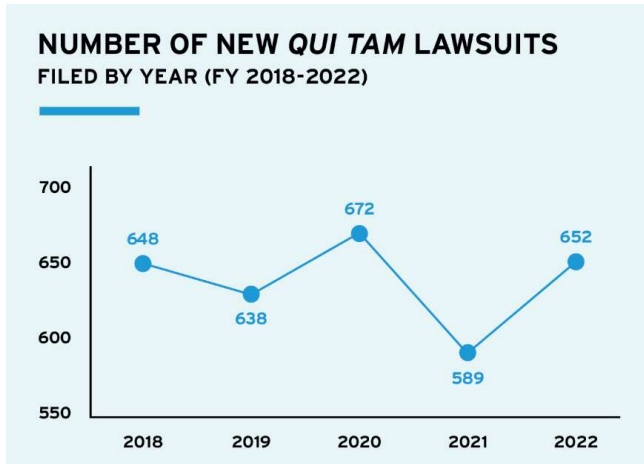
80% of civil fraud recoveries (\$1.76B) from healthcare industry

Over \$25 billion recovered from healthcare industry over last 10 years

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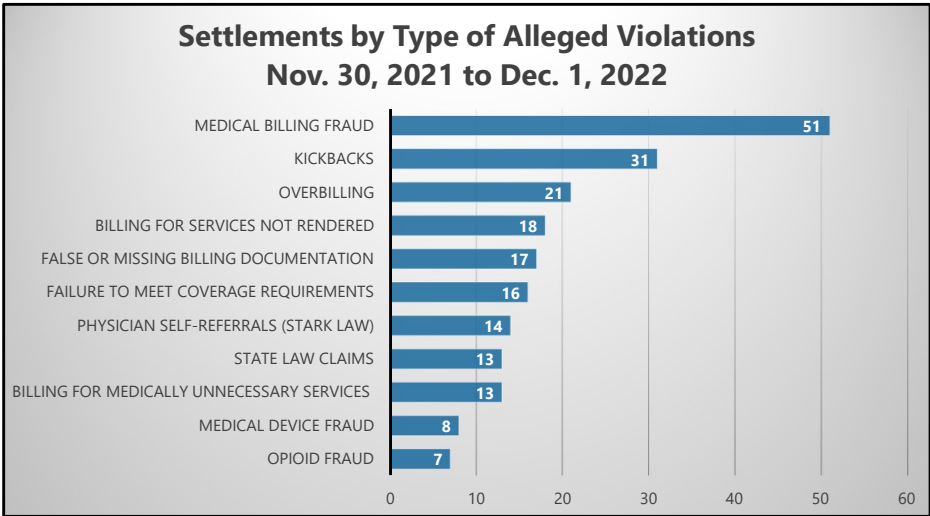
QUI TAMS DRIVE ENFORCEMENT



652 newly-filed *qui tam* lawsuits in FY2022

More than 6,500 *qui tam* lawsuits filed over the last 10 years

ENFORCEMENT TRENDS



◆ Billing & Coding

◆ Kickbacks

NATIONAL HEALTHCARE FRAUD TAKEDOWN



- \$1.2 billion in false or fraudulent claims
- Involved telemedicine, clinical labs, and DME
- \$1 billion out of \$1.2 billion pertained to telemedicine
- 36 defendants; 13 federal districts

Justice Department Charges Dozens for \$1.2 Billion in Health Care Fraud
Nationwide Coordinated Law Enforcement Action to Combat Telemedicine, Clinical Laboratory, and Durable Medical Equipment Fraud

TELEHEALTH: ENFORCEMENT

- ◆ Telehealth schemes can have wide ranging effects
 - \$73 million scheme → allegedly involved billing for telemedicine encounters that did not occur and ordering of unnecessary genetic testing



OVERVIEW OF RPM/RTM

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WHAT'S IN A NAME?

◆ RPM

- Remote Patient Monitoring
- Remote Physiological Monitoring

◆ RTM

- Remote Therapeutic Monitoring
- Remote Treatment Management



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RPM



◆ RPM

- Use of digital health technologies to collect health data from patients in one location and electronically transmit that information securely to providers in a different location
- Non-face-to-face monitoring and analysis of physiologic factors used to understand a patient's health status
- Data can include vital signs, weight, blood pressure, blood sugar, pacemaker information, etc.
- Includes collection and analysis of physiological data
- Data used to develop and manage a treatment plan
- Can be related to either a chronic condition or an acute illness

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RTM




◆ RTM

- Non-face-to-face monitoring and analysis of non-physiologic factors used to understand a patient's health status
- Monitor patient's adherence to a care plan (including medication or lifestyle habits), as well as musculoskeletal system and respiratory system functions
- Data includes non-physiological data (e.g., pain levels, exercise programs)
- Data can be self-reported through smartphone app or online platform

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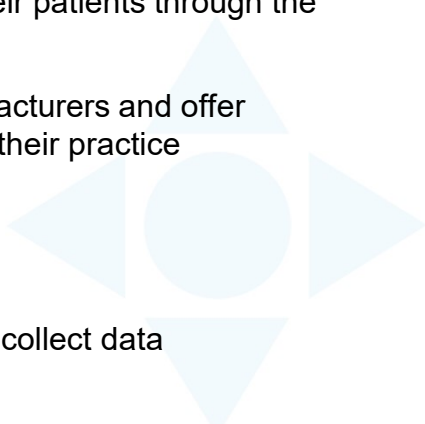
STRUCTURING RPM/RTM ARRANGEMENTS



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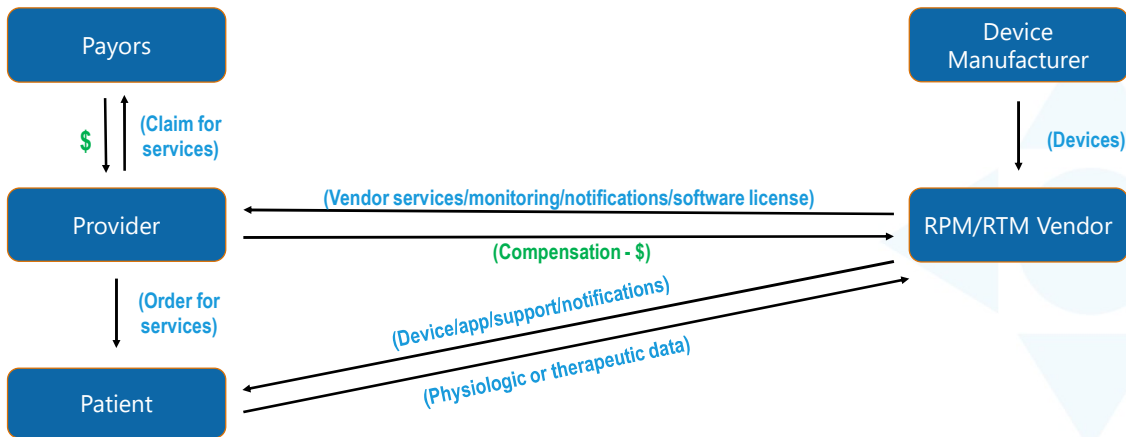
KEY PLAYERS

- ◆ **Providers** – remotely review data collected by the devices for their patients through the vendor's platform
 - ◆ **RPM/RTM Company** – maintain relationships with device manufacturers and offer RPM/RTM capabilities as a service for providers to implement in their practice
 - ◆ **Payors** – reimburse providers for RPM/RTM services
 - ◆ **Patients** – submit physiologic or therapeutic data for review
 - ◆ **Device Manufacturers** – makers of the medical devices used to collect data
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TYPICAL STRUCTURE



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COMPETING INTERESTS

PROVIDER

- ◆ Patient care
- ◆ Revenue
- ◆ Ease of use
- ◆ Value-based reimbursement

RPM/RTM COMPANY

- ◆ Turnkey solution
- ◆ Growth
- ◆ Revenue
- ◆ Data rights
- ◆ Promote other services

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KEY CONTRACTUAL CONSIDERATIONS

◆ Responsibilities of the parties

- Who bills?
- Who collects (payor and patient)?
- Who provides the equipment?
- Who obtains informed consent?
- Who performs what services?
- What are monitoring parameters?
- Who tracks usage?
- Who documents what?

◆ Structure of payment

- ◆ Value and ownership of equipment
- ◆ Ownership and access to data
- ◆ Licensure and supervision of staff
- ◆ Privacy/security
- ◆ Software license
- ◆ Liability/indemnification

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RPM/RTM COVERAGE

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HISTORY OF RPM/RTM COVERAGE

Medicare

- ◆ 2018
 - Initial coverage of collection and interpretation of physiological data
- ◆ 2019
 - RPM coverage
- ◆ 2022
 - RTM coverage
- ◆ CMS guidance continues to evolve each year...

Other Payors

- ◆ Medicaid coverage varies by state
- ◆ Commercial coverage varies by payor and contract

RPM CODES

Service Initiation (CPT 99453)	Data Transmission (CPT 99454)	Treatment Management (CPT 99457, 99458)	Data Analysis & Interpretation (CPT 99091)
<ul style="list-style-type: none"> • Remote monitoring of physiologic parameter(s) [e.g., weight, blood pressure, pulse oximetry, respiratory flow rate], initial; set-up and patient education on use of equipment • \$19.32 (2023) 	<ul style="list-style-type: none"> • Remote monitoring of physiologic parameter([e.g., weight, blood pressure, pulse oximetry, respiratory flow rate], initial; each 30 days • \$50.15 (2023) 	<ul style="list-style-type: none"> • Remote physiologic monitoring treatment management services, clinical staff, physician, other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; initial 20 minutes and additional 20 minutes • \$48.80/\$39.65 (2023) 	<ul style="list-style-type: none"> • Collection and interpretation of physiologic data [e.g., ECG, blood pressure, glucose monitoring] digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified healthcare professional, qualified by education, training, licensure/ regulation [when applicable] requiring a minimum of 30 minutes of time, each 30 days • \$54.22 (2023)

RPM MEDICARE COVERAGE

- ❖ Ordered and billed by physicians/non-physician practitioners who can bill for E/M services
- ❖ Requires use of device that meets the definition of “medical device” stated in Section 201(h) of the Federal Food, Drug and Cosmetic Act
- ❖ Device must automatically upload patient data
- ❖ Need to obtain and document patient consent, including acknowledgement of financial responsibility
- ❖ Must have established relationship with the patient (post-PHE change)
- ❖ Services must be reasonable and medically necessary
- ❖ Service must be “used to develop and manage a treatment plan related to a chronic and/or acute health illness or condition”

RTM CODES

Initial Set Up (CPT 98975)

- RTM initial set-up and patient education on use of equipment
- \$19.32 (2023)

Data Transmission (CPT 98976, 98977, 989X6)

- RTM status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/ or programmed alert(s) transmission to monitor respiratory system/musculoskeletal system/cognitive behavioral therapy, each 30 days
- \$50.15/contractor price (2023)

Treatment Management (CPT 98980, 98981)

- RTM treatment, physician/other qualified healthcare professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; initial 20 minutes and CPT 98981 for additional 20 minutes
- \$49.48/\$39.65 (2023)

RTM MEDICARE COVERAGE

- ✦ Ordered and billed by physicians, non-physician practitioners, physical/occupational therapists, speech language pathologists, clinical social workers
- ✦ Requires use of device that meets the definition of “medical device” stated in Section 201(h) of the Federal Food, Drug and Cosmetic Act
- ✦ Device does not have to automatically upload patient data; data may be uploaded by patient (differs from RPM)
- ✦ Need to obtain and document patient consent, including acknowledgement of financial responsibility
- ✦ Established relationship with patient NOT required (at this time)
- ✦ Services must be reasonable and medically necessary
- ✦ Service must be used to monitor respiratory system, musculoskeletal system, or cognitive behavioral therapy

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RPM/RTM MEDICARE COVERAGE CHANGES FOR 2024

- ✦ Established patient
 - Clarified that established patient means new patient E/M visit and treatment plan
 - Required for RPM
 - Not required for RTM (at this time)
- ✦ 16 days of data collection in 30 day period required
 - To bill service initiation (CPT 99453, 98975) or data transmission (CPT 99454, 98976, 98977, 989X6)
 - Not to bill treatment management (CPT 99457, 99458, 98980, 98981)
- ✦ FQHCs and RHCs may receive separate reimbursement for RPM/RTM services (new for 2024)

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RPM/RTM MEDICARE COVERAGE CHANGES FOR 2024

- ✦ Only one practitioner can bill Medicare for RPM/RTM (but not both)
 - Regardless of how many devices provided or conditions being monitored
- ✦ RPM/RTM (but not both) can be billed with certain care management services, so long as time and effort is not counted more than once
 - Chronic Care Management (CCM)
 - Transitional Care Management (TCM)
 - Behavioral Health Integration (BHI)
 - Principal Care Management (PCM)
 - Chronic Pain Management (CPM)
- ✦ Practitioner subject to global surgery period cannot bill for RPM/RTM
 - Limitation does not apply to other practitioner (not subject to global surgery) who can bill for RPM/RTM
- ✦ RPM not included in definition of primary care services for MSSP

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RPM/RTM COMPLIANCE RISKS

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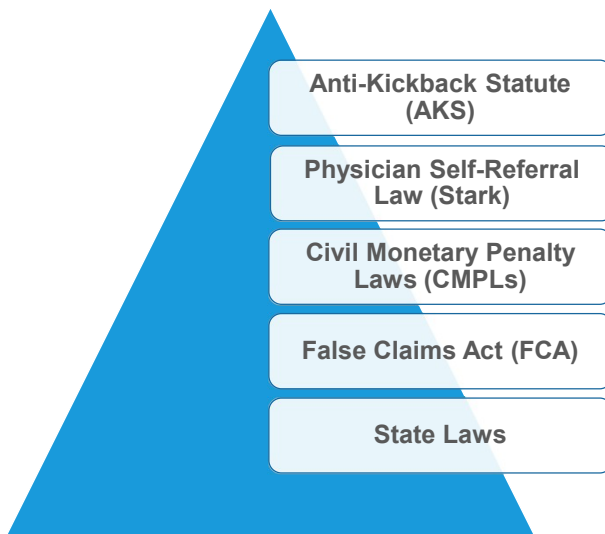
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WHAT ARE THE COMPLIANCE RISKS?

- ◆ Fraud & abuse
- ◆ Billing & coding
- ◆ Overutilization
- ◆ Adequate supervision
- ◆ Beneficiary copayment obligations
- ◆ Data privacy/security
- ◆ Licensing



FRAUD AND ABUSE



FRAUD & ABUSE



◆ Compensation to RPM/RTM Company

- How much? FMV?
- Fixed fee? Per-click?
- What services does fee cover?

◆ Free services

- Does RPM/RTM Company provide free services?
- Does it not charge for certain services?

◆ Patient Devices

- What's the value?
- Who owns the device?
- Who's responsible for loss/damage?



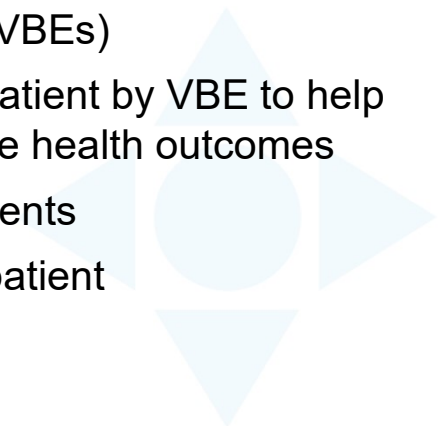
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FRAUD & ABUSE

◆ Patient Engagement and Support Safe Harbor

- AKS Safe Harbor for Value-Based Enterprises (VBEs)
- Protects tools and support provided directly to patient by VBE to help ensure adherence to treatment plan and improve health outcomes
- In-kind remuneration only, no cash/cash equivalents
- Aggregate retail value up to \$500 per year per patient



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BILLING & CODING

❖ Have all requirements to bill RPM/RTM services been satisfied (and documented)?

- Rules may vary depending on date of service and payor

❖ Challenge created

- Intent to obtain (or retain) federal funds to which you are not entitled
- Not innocent mistakes
- ...where is line between intentional conduct (reckless disregard) and mistakes

RPM CODES	RTM CODES
99453	98975
99454	98976
99457	98977
99458	989X6
99091	98980
	98981

BILLING & CODING

❖ Compliance takeaways

❖ Compliance program

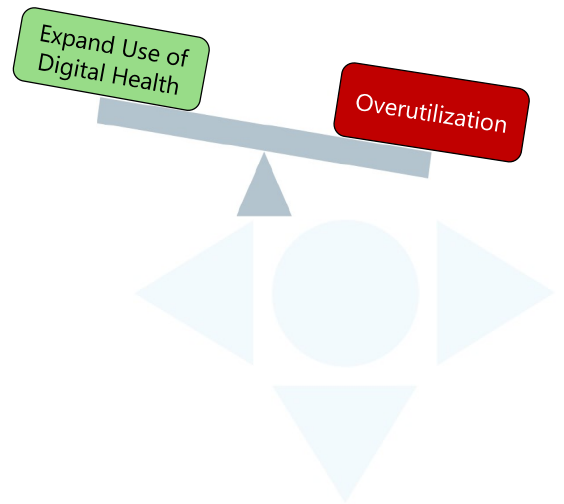
- Encourage questions and reporting
- Risk assessment
- Audits
- Corrective actions

❖ Growing use of data analytics

- Address overpayments timely
→ avoid retaining overpayments

OVERUTILIZATION

- ◆ Key concern for gov't
- ◆ Who identifies patients who would benefit from RPM/RTM?
 - What role does physician play?



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ADEQUATE SUPERVISION

- ◆ Important for billing, licensure, and patient care
- ◆ Role of RPM/RTM company



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BENEFICIARY COPAYMENT

- ◆ Varies by payor
- ◆ Medicare – 20% beneficiary copay
- ◆ COVID-19 PHE permitted copay waiver for RPM and telemedicine
- ◆ Beneficiary copay not generally waiveable
 - Except for financial need



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DATA PRIVACY/SECURITY

- ◆ HIPAA and state privacy laws
 - What data is being transmitted?
 - Where is it stored?
 - How is it being used by the parties?
- ◆ HIPAA business associate agreements
- ◆ HIPAA authorizations from patients



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LICENSING

- ◆ Services provided across state lines – what licenses are required?
- ◆ Related concern about services performed outside the U.S.

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**DON'T FORGET ABOUT
THE DATA**

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VALUE AND USAGE OF DATA

- ❖ With growing usage of artificial intelligence and big data and greater understanding of potential utility in identifying and addressing healthcare issues, there is growing recognition of value of healthcare data
- ❖ Consider who holds what rights to data
- ❖ Collaborative arrangements can create valuable data
- ❖ Understand limits and protections imposed by federal HIPAA and state privacy laws
- ❖ Recognize complexities around “de-identified patient data”
- ❖ Need to consider fair market value questions under various legal authorities, including AKS, Stark, and non-profit tax laws

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VALUE AND USAGE OF DATA

- ❖ Even within organizations, must think about how data is used.
- ❖ Data can be used for legitimate purposes, such as identifying potential quality concerns, areas for improvement, or dissatisfaction with services
- ❖ Data can also be used for inappropriate purposes, such as violating AKS or Stark
- ❖ Need to consider ground rules about how data is used within an organization

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TIME FOR QUESTIONS



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FINAL THOUGHTS

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PRACTICAL TAKEAWAYS

- ✦ Consider Compliance Program Updates
 - Ensure relevant policies are in place
 - Assess training needs
 - Consider new risks as part of annual risk assessment
- ✦ Appropriate Coding/Billing
 - Upfront policies
 - Training
 - Coding/billing reviews
- ✦ **Need to Monitor Ongoing Changes**
 - CMS billing and coding changes
 - OIG guidance
 - State licensing



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PRACTICAL TAKEAWAYS

- ✦ Review Arrangements
 - Who is doing what?
 - Compensation mechanisms
- ✦ Privacy Concerns
- ✦ Security Concerns
- ✦ Data Breach Response Plan
- ✦ Due Diligence Considerations
 - What questions need to be asked



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THANK YOU



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