Telehealth 2021: Regulatory and Reimbursement Developments

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Disclaimer

- The views presented during this session do NOT constitute legal advice. These views also do NOT necessarily reflect the views of the panelists' respective employers.

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Agenda

- Recent Developments in Telehealth and Telehealth Regulation
- CMS's Carve Out of Remote Patient Monitoring and Remote Therapeutic Monitoring from Telehealth
- Private Insurance and Telehealth

Recent Developments in Telehealth and Telehealth Regulation

Kyle Thomson

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Defining the Telehealth Landscape

Telehealth

- Synchronous
- Real-time, audio-video communication that connect physicians and patients in different locations (Note: This definition is used for telehealth for CMS coverage and payment.)
- Real-time audio and telephone communications

Asynchronous

- Store-and-forward technologies that collect images and data to be transmitted and interpreted later
- Online digital visits and/or brief check-in services furnished using communication technology that are employed to evaluate whether or not an office visit is warranted (via patient portal, smartphone)
- Interprofessional internet consultations between physicians and/or other qualified health care professionals to improve care coordination for patients by sharing verbal or written reports for further assessment and/or care management

Audio-Only

- Some insurance plans and state regulators consider audio-only care to be a form of telehealth. CMS recently expanded the definition of "telecommunications system" in section 1834(m) of the Social Security Act to include audio-only services for purposes of mental health telehealth services.

Remote patient-monitoring (RPM)

- RPM is patient data being collected and transmitted outside of the office, mostly asynchronous, which results in clinical decision making and care management follow up that may be provided in-person or virtually.
- Tools and wearable devices (which may involve the use of mHealth apps) that measure weight, blood pressure, pulse oximetry, respiratory flow rate and other parameters communicate biometric data for review and treatment management.

Medicare Coverage Prior to the COVID-19 Pandemic

- Section1834(m) of the Social Security Act generally restricts CMS from covering telehealth services unless they “originate” from certain sites – generally, a qualified healthcare facility – in rural geographic locations.
- In practice, this means most Medicare beneficiaries cannot access telehealth services unless they live in a rural location and travel to a physician’s office or other qualifying site.

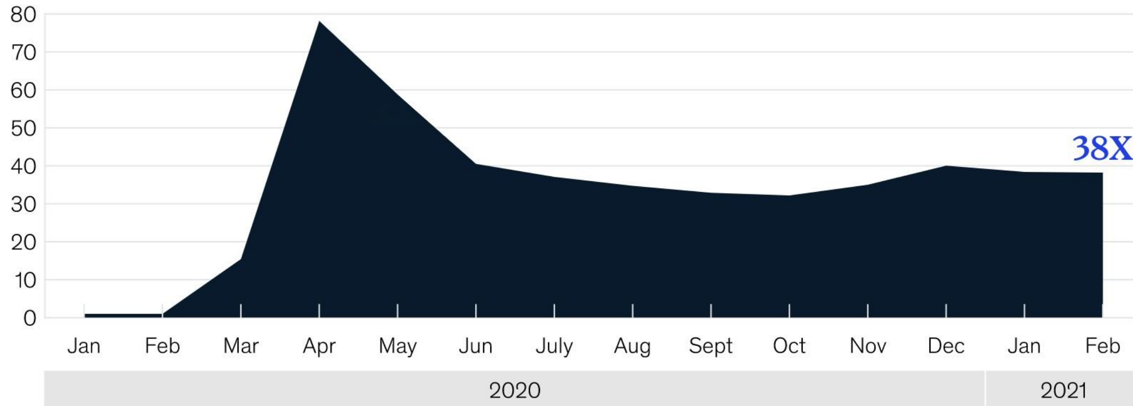
Regulatory Changes to Telehealth Coverage in Response to the COVID-19 Pandemic

- Congress provided CMS with authority to waive these requirements for the duration of the COVID-19 PHE.
- States issued PHE declarations with waivers for telehealth requirements
  - Note, however, that many of these waivers have been rescinded or expired
- Pursuant to this waiver authority, during public health emergency, CMS has:
  - Allowed for physicians to provide telehealth to Medicare patients nationwide, not just rural locations;
  - Permitted patients to receive telehealth services in their homes;
  - Added interim coverage for more than 150 services for the duration of the COVID-19 PHE (most of which it has now guaranteed coverage through the end of 2023).
  - Increased payment for telehealth services to be equivalent to in-office rates;
  - Provided flexibility to allow for a patient-physician relationship to be established via telehealth platforms in many circumstances.
- In addition HHS Office for Civil Rights issued guidance exercising enforcement discretion over the use of non-HIPAA compliant apps like FaceTime, Facebook Messenger, Google Hangouts, Zoom, Skype, etc.
  - This does not include public facing apps (eg, Facebook Live, TikTok)

Increase in Telehealth Usage During the PHE

- According to the Assistant Secretary for Planning and Evaluation (ASPE) at the Department of Health and Human Services (HHS), before the public health emergency (PHE), 14,000 patients received a Medicare telehealth service in a week, while in the early days of the pandemic, over 10.1 million patients received a Medicare telehealth service from mid-March through early-July of 2020. Telehealth visits accounted for 43.5 percent of all primary care visits for Medicare beneficiaries during that timeframe.
- More than 25% of all Medicare beneficiaries reported having a telehealth visit during Summer and Fall of 2020.
- Patients' views on telehealth are shifting as well. In a recent survey by the COVID-19 Healthcare Coalition, 79 percent of patient respondents reported satisfaction with their telehealth visit and 78 percent felt that their health concern could be addressed via telehealth. In addition, 83 percent of patients felt communication with their physician during their telehealth visit was strong.

Increase in Telehealth Usage During the PHE



- Claims data from private insurers paint a similar picture: even after a decline from usage highs in the early pandemic, Telehealth usage remains at dramatically higher levels than prior to the pandemic.

Source: McKinsey & Company, “Telehealth: A quarter-trillion-dollar post-COVID-19 reality?”

Telehealth Post Pandemic

- Without action from Congress, most Medicare beneficiaries will lose access to the majority of telehealth services.
- It is likely that the current waivers, including those covering telehealth services, will be extended one to two years after the end of the PHE.
- In recent rulemaking, CMS expanded its definition of telehealth services to include audio-only services for mental health services. Potential for increased regulatory flexibility in the future.

Remote Physiologic and Therapeutic Monitoring (RPM and RTM)

Lidia Niecko-Najjum

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Telehealth Carve Out - RPM Codes

99453 Remote monitoring of physiologic parameter(s): Initial set-up time, including patient education on use of equipment. This is a practice expense only code.

99454 Remote monitoring of physiologic parameter(s): Initial device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days. This is a practice expense only code. Monitoring must take place for at least 16 days to be applied.

99457 Remote physiologic monitoring treatment management services: **20 minutes or more** of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month.

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**

RPM Guidelines

Use

- Primary billers expected: physicians or other practitioners eligible to bill Medicare for E/M services; auxiliary personnel (e.g., nonclinical staff) may bill 99453 or 99454 as incident to under general supervision (care management service)
- Interactive communication (99457, 99458) must at minimum be real-time synchronous, two-way audio interaction and can include provider time engaged in non-face-to-face care management services
- Established patients only (except during the PHE); consent may be obtained at time of service

Medical Device

- Technology must meet definition of medical device in FD&C
  - Software as a medical device (SaMD) that could fall under enforcement discretion;
  - Hardware is a separate analysis

Data Collected

- Monitoring must occur at least 16 of 30 days per month (except during PHE)
- Physiologic and digitally uploaded.

CY 2022 RTM Codes

Code	Description
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	Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days
98977	Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days
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 (List separately in addition to code for primary procedure)

RTM Codes - Guidelines

Use

- Primary billers expected: nurses and PTs but cannot bill unless NPP or Physician
- General medicine codes (“incident to”/direct supervision; not E/M codes and so not care management codes (general supervision))
- At least one interactive communication (98980, 98981); can be billed as “sometimes therapy” codes (outside a therapy plan of care by a physician and certain NPPs when appropriate)

Medical Device

- Technology must meet definition of medical device in FD&C

Data Collected

- Non-physiologic and “reportedly” self reported
- CMS stated in the CY 2022 PFS proposed rule that “according to the code descriptors, RTM codes monitor health conditions, including musculoskeletal system status, respiratory system status, therapy (medication) adherence, and therapy (medication) response, and as such, allow non-physiologic data to be collected. Reportedly, data also can be **self-reported as well as digitally uploaded**.”

FDA Oversight of Digital Technology

Not a medical device

Examples

- Personal health records
- Mobile apps to help patients document, show or communicate information to providers (e.g., videoconferencing for telehealth)
- Electronic health record

Medical device BUT enforcement discretion

Examples

- Software that automates simple tasks for health care providers
- **Tools that help individuals manage their disease without specific treatment or suggestions (e.g., medication tracking or adherence**)
- Mobile apps that use cameras for documenting wounds or skin conditions
- Non-device MDDS – intended to transfer, store, display medical device data

Medical device subject to FDA oversight

Examples

- Software that performs patient-specific analysis for diagnosis or treatment recommendations or is an extension of a medical device.

RPM/RTM - Limitations

RPM

- General supervision/liability by billing provider
- FDA Medical Device
- Monitoring – 16 out of 30 days (PHE shorter)
- Live Interaction

RTM

- Direct supervision
- FDA Medical Device
- Live Interaction

Insurers in Digital Health

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Insurers in Digital Health

- Symptom Checkers, Immediate Information, drug interactions, disease specific (chronic)
  - FDA regulated software? Or Not? Role of Clinical Decision Support (Patient Decision Support)
- Quick Access to Telemedicine/Telemental Health

Insurers in Digital Health

- Challenges with “Digital First” Health Insurance
  - Credentialing (and Medicare/Medicaid overlap)
    - Role of COVID waivers
  - Claims documentation and coding (AMA license issues)
  - Risk adjustment and service/interaction definition
  - Administrative v. Medical
    - Vendor v. Provider (tech driven or provider driven – both?)
  - Pricing and Reimbursement
    - Payor of Claims v. Purveyor of Services

DTC in Digital Health

- "Retail" Digital Health
  - DTC offering driven by consumer choice
    - Blending digital and physical care
  - Who? Tech and retail giants, fitness companies and tech/health start ups
    - Lacking deep healthcare market or regulatory expertise
    - Leveraging strong technology assets and customer acquisition tools

DTC in Digital Health

- Challenges with DTC Telehealth
  - State insurance regulation impacting pricing models (subscriptions)
  - Discount Medical/Pharmacy Plan rules (consumer protection)
  - Corporate Practice of Medicine (CPOM) and practice of professions (pharmacy/laboratory)
  - Platform offering (v. since vertical)
    - Fraud and abuse issues on internal referrals

DTC in Digital Health

- FDA regulated software? Or Not? Role of Clinical Decision Support (Patient Decision Support)
- Standard of Care
  - Licensure, scope of practice, establishment of care
    - Role of COVID 19 waivers

Q&A

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