

Latham & Watkins Healthcare Regulatory Practice

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Healthcare Coverage Developments on the Horizon for Emerging Technologies, Including Digital Technologies

Technology companies, providers, investors, and other stakeholders should prepare for potential policy changes.

In the coming months, a number of significant developments are anticipated to influence the future of the Medicare program's coverage policies with respect to digital technologies. These developments relate to coverage for remote physiological monitoring (RPM) and remote therapeutic monitoring (RTM) services, as well as possible policy changes relating to termination of the COVID-19 pandemic public health emergency.

Advisory Committee Meeting Targeting Remote Monitoring — Feb. 28

On February 28, 2023, six of the seven Medicare Administrative Contractors (MACs) will host a multijurisdictional Contractor Advisory Committee (CAC) meeting to discuss coverage for RPM and RTM services. The <u>purpose</u> of the meeting is "to obtain advice from CAC members and subject matter experts regarding the strength of published evidence on [RPM] and [RTM] for non-implantable devices and any compelling clinical data to assist in defining meaningful and measurable patient outcomes (e.g., decreases in emergency room visit and hospitalizations) for our Medicare beneficiaries to assist in the determination of whether [a local coverage determination (LCD)] should be developed."

RPM services describe the collection and analysis of patient physiologic data that are used to develop and manage a treatment plan related to a chronic and/or acute health illness or condition. The RPM code set consists of five codes created by the Current Procedural Terminology (CPT) Editorial Panel in September 2017 (including revisions to legacy code 99091) and assigned national Medicare payment rates effective January 2019. The code set includes two practice-expense (PE) only codes for initial setup and device supply (99453 and 99454, respectively). It also includes three professional work codes — one legacy Medicare code that describes the collection and interpretation of physiologic data, which must be personally performed by the billing practitioner (99091), and two new codes that describe RPM treatment management services, which can be furnished by clinical staff under the general supervision of the billing practitioner (99457 and add-on code 99458).

Remote Physiologic Monitoring — CPT Code Descriptors

HCPCS	RPM Descriptor
99453	Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; setup and patient education on use of equipment
99454	Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days
99457	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; first 20 minutes
99458	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; each additional 20 minutes (List separately in addition to code for primary procedure)
99091	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

The services and code structure of the RTM code set resemble those of RPM. However, the specific equipment used is different because the data being monitored are non-physiologic (rather than physiologic as with RPM), although currently the codes are limited to monitoring of certain conditions only (musculoskeletal, respiratory, and cognitive behavioral therapy). The RTM code set was created by the CPT Editorial Panel in October 2020 and includes three PE-only codes for initial setup (98975) and device supply (98976 and 98977), and two codes that include professional work (98980 and add-on code 98981). CMS assigned national Medicare payment rates for the RTM codes effective January 2022.

Remote Therapeutic Monitoring — CPT Code Descriptors

HCPCS	RTM Descriptor
98975	Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial setup 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

HCPCS	RTM Descriptor
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
98978	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 cognitive behavioral therapy, each 30 days
98980	Remote therapeutic monitoring treatment management services, physician/other qualified healthcare 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 healthcare 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)

Use of the RPM and RTM code sets has generally increased since the codes were established,¹ likely in part due to various waivers and flexibilities during the COVID-19 pandemic that have expanded providers' ability to offer these services. This pattern is consistent with the general increased interest in telehealth and telemedicine services during the pandemic. As the pandemic winds down, auditing and enforcement of Medicare coverage and payment requirements for remote monitoring services and other digital health technologies and services is expected to increase. For example, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) Work Plan projects the release of a report on audits of Part B telehealth services in 2023. Medicare contractor interest in developing an LCD for RPM and RTM services could also indicate an interest in establishing more specific or more limited coverage criteria for these services.

The February 28 CAC meeting will be held via webinar only and will be open to industry stakeholders and members of the public. Only CAC members, subject matter experts, and the MACs' RPM/RTM national work group contractor medical directors (CMDs) may participate in the meeting. The CAC meeting announcement is available on several of MACs' websites (example here). Additional details around the February 28 CAC meeting — including background material, discussion questions, agenda, and registration — will likely be available on MACs' websites by February 14, 2023.

End of COVID-19 PHE — May 11

The Biden Administration recently announced plans to terminate the national emergencies connected to the COVID-19 pandemic on May 11, 2023. The end of the public health emergency (PHE) will result in the expiration of numerous emergency health policies in effect only for the duration of the PHE. These policies include provisions expanding coverage and access to certain items/services to millions of Americans and temporary flexibilities that many patients and providers have come to depend on. Congress has taken steps to extend the period of time that certain waiver-related policies will remain in effect, and CMS has developed a <u>roadmap</u> for the eventual end of the Medicare PHE waivers and flexibilities. However, various questions remain on how CMS will adapt to specific policy changes that,

if reversed, could disrupt continuity of care for those beneficiaries and providers who have come to rely on these waivers.

Looking Ahead

Stakeholders, including technology companies, providers, and investors should consider a number of steps in relation to these policy developments. Notably, the following questions should be assessed:

- Does the organization have a leader charged with actively monitoring these and other similar developments, including how trade associations, competitors, and business partners are engaging?
- Does the organization have a multidisciplinary team informing its analysis and multifaceted response (legal, policy, compliance, and operational) to these dynamic developments?
- Has the organization assessed the most likely potential outcomes related to each of these policies and worked with competent advisors to assess the likelihood of each outcome, impact on the organization, and response?
- Does the organization have the resources to harness the emerging data to assess the marketplace and its place therein? What strategic threats and opportunities might the data illustrate?
- Does the organization have an evidence-based strategy to support the value of its technology, investment, or technology enabled service?
- Finally, is the organization poised to make a thoughtful (but quick) decision about actively engaging or not in one or more of the emerging policy debates?

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Endnote

¹ See, e.g., CMS public use file, Utilization Data Crosswalks for CYs 2019–2023.