SPECIAL REPORT

REMOTE MONITORING UPDATES: CMS CLARIFIES GUIDANCE, PROPOSES RURAL PROVIDER PAYMENT, REQUESTS INFORMATION ON DIGITAL THERAPEUTICS

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SUMMARY

Over the past several years, the Centers for Medicare and Medicaid Services (CMS) has expanded payment for care management and remote monitoring services in an effort to recognize and pay for non-face-to-face services that improve care coordination for Medicare beneficiaries. In connection with the calendar year 2024 Medicare Physician Fee Schedule (MPFS) proposed rule, CMS clarifies its existing guidance for remote monitoring services, including both remote physiological monitoring (RPM) and remote therapeutic monitoring (RTM) services, and proposed several additional clarifications. CMS requests additional information from healthcare providers and other stakeholders regarding the use of remote monitoring, remote cognitive behavioral therapy (CBT) and other digital therapeutic modalities.

CMS also proposes modifications to the way rural health centers (RHCs) and federally qualified health centers (FQHCs) are reimbursed for care management services, and proposed to establish reimbursement for remote monitoring services furnished by RHCs and FQHCs. Comments and responses to the requests for information included in the proposed rule are due to CMS by September 11, 2023.

IN DEPTH

BACKGROUND

In recent years, CMS expanded payment for a variety of care management services, with the intention of recognizing and paying for non-face-to-face care management services that may not be appropriately captured by existing codes for in-person patient encounters. This trend arguably began with the establishment of separate reimbursement for chronic care management services in 2013 but has since expanded to encompass complex chronic care management, principal care management and other specialized codes. Care management services are patient management and support services that are frequently provided by clinical staff under the direction of a physician or other qualified healthcare professional, but may also be directly furnished by a physician, nurse practitioner or physician assistant.

Remote monitoring generally uses digital technologies (medical devices, together with software) to collect medical and other forms of health data from patients in one location and electronically transmit the information to the patient's healthcare provider in a different location for assessment and patient care management. In some cases, the technologies can either trigger direct patient engagement or facilitate that communication with a healthcare provider. Remote monitoring services are frequently used for care management in between in-person visits with a healthcare provider.

Beginning in 2019, CMS established payment rates for RPM services under the MPFS and provided guidance on certain requirements and appropriate utilization for remote monitoring services. With the creation of specific codes for RTM services in 2022, CMS established separate payment for RTM services.

REMOTE MONITORING UPDATES FOLLOWING TERMINATION OF THE COVID-19 PHE

In response to the COVID-19 PHE, CMS also issued several waivers and flexibilities that expanded clinicians' ability to furnish remote monitoring services to patients, including flexibilities regarding could furnish the services, the types of technology that could be used and how many days of monitoring had to be obtained in order to bill. CMS previously established that its interim policies would expire on May 11, 2023, the last day of the COVID-19 PHE.

CMS indicates in the 2024 MPFS proposed rule that it has received many questions about various billing scenarios and requests for clarifications on the appropriate use of RPM and RTM codes. CMS reiterates the following clarifications, many of which were previously stated in regulatory preambles:

- RPM services may only be furnished to established (as opposed to new) patients. Patients who initially received remote monitoring services during the PHE are considered to be established patients for purposes of remote monitoring services that are furnished after the end of the PHE.
- The RPM and RTM codes require data collection for at least 16 days in a 30-day period. This minimum data collection

requirement was temporarily waived during the PHE, but this flexibility was not extended post-PHE.

- For both RPM and RTM services, only one practitioner can bill the codes during a 30-day period.
- RPM and RTM services require that data be gathered using a medical device as defined by the Federal Food, Drug, and Cosmetic Act, and regardless of how many medical devices are provided to a patient, the services associated with all medical devices can be billed only once per patient, per 30-day period.

In addition to reiterating previous guidance related to RPM and RTM services, CMS proposes several clarifications for appropriate billing of these services. CMS has previously clarified, and reiterated in the proposed rule, that healthcare practitioners may bill RPM or RTM concurrently with other care management services, including chronic care management, transitional care management, primary care management, behavioral health integration and chronic pain management services. CMS proposes to clarify, consistent with the 2023 CPT Codebook guidance for these codes, that RPM and RTM may not be billed together. This prohibition is intended to ensure that time associated with remote monitoring services is not counted twice.

CMS also proposes to clarify that RPM or RTM services may be furnished to patients who are within a global period for surgery. However, the remote monitoring services must be unrelated to the diagnosis for which the surgery or procedure is performed, and the purpose of the remote monitoring must be to address an episode of care that is separate and distinct from the episode of care for the global procedure.

REQUEST FOR INFORMATION ON DIGITAL THERAPIES AND REMOTE MONITORING

As noted above, CMS has expanded Medicare payment for technologies that are used for remote monitoring of treatment and physical health. The US Food and Drug Administration has reviewed and cleared several mobile medical applications that are intended to address a variety of health conditions. CMS requests information on how digital technologies and remote monitoring services are used in clinical practice, together with opportunities and challenges on coding, payment policies and claims processing for digital therapies.

More specifically, CMS requests information on the following topics:

- How do practitioners determine which patients might be best served by digital therapeutics? How do practitioners monitor the effectiveness of prescribed interventions for their patients on an ongoing basis once the intervention has begun?
- CMS seeks comment on, and real-life examples of, scenarios where digital CBT or other digital-enabled therapy services are used by clinicians, and how the technology is embedded in various practice models. For example, how is the patient evaluated and/or how is the treating clinician involved in the services received when the patient participates in digital CBT?

- What standards have interested parties developed or consulted to ensure the physical safety and privacy of beneficiaries utilizing digital CBT and/or other digital therapeutics for behavioral health?
- What are effective models for distribution/delivery of digital therapeutics, such as prescription digital mental health therapy products, to patients? What best practices exist to ensure that patients have the necessary support and training to use applications effectively?
- What practitioners and auxiliary staff are involved in furnishing RPM and RTM services, including training patients on its use, and to what extent is additional training or supervision of auxiliary staff necessary to provide an appropriate and/or recommended standard of care in the delivery of these services?
- How are data collected by the technology maintained for recordkeeping and care coordination?
- What information exists about how an episode of care should be defined, particularly in circumstances when a patient may receive concurrent RTM or digital CBT services from two different clinicians engaged in separate episodes of care?
- As noted above, even when multiple medical devices are provided to patient, the services associated with all the medical devices can be billed by only one practitioner, only once per patient, per 30-day period, and only when at least 16 days of data have been collected. What are the type and frequency of circumstances that involve multiple medical devices and multiple clinicians? How might allowing clinicians to bill for multiple concurrent RTM services for an individual beneficiary affect access to healthcare, patient out-of-pocket costs, quality of care, health equity and program integrity?
- Do interested parties believe digital CBT could be billed using the existing RTM codes described by CPT codes 98975, 98980 and 98981? What impediments may exist to using these codes for digital CBT?
- What scientific and clinical evidence of effectiveness should CMS consider when determining whether digital therapeutics for behavioral health are reasonable and necessary?
  - » What are the advantages and disadvantages of a generic RTM device code versus specific RTM codes?
  - » Would generic device codes undermine or stall progress toward a wider set of specific codes that would provide less ambiguity on reimbursement?
  - » How might generic RTM codes for supply of a device be valued given the broad array of pricing models?
- What aspects of digital therapeutics for behavioral health should CMS consider when determining whether they fit into a Medicare benefit category, and which category should be used?
- If CMS determines the services fit within an existing Medicare benefit category or if other coverage requirements are met, what aspects of delivering digital CBT services should be considered when determining potential

Medicare payment? Under current practice models, are these products used as incident-to supplies or are they used independent of a patient visit with a practitioner? If used independently of a clinic visit, does a practitioner issue an order for the services?

- Are there barriers to digital CBT reaching underserved populations, and would a supervision requirement impact access to digital CBT for underserved populations?
- What role, if any, do digital therapeutics for behavioral health play in supporting disadvantaged/hard to reach populations in advancing equity in healthcare services?
- What are some potential considerations for protecting the privacy and confidentiality of the patient population in digital therapeutics, including compliance with state behavioral health privacy requirements?

REMOTE MONITORING SERVICES FURNISHED BY RHCS AND FQHCS

RHC and FQHC Reimbursement Background

Both RHCs and FQHCs are paid under reimbursement systems that are intended to reflect the cost of all services provided by the RHC or FQHC to a patient in a single day. In general, RHCs are paid an all-inclusive rate (subject to a payment limit) for all medically necessary services furnished to a patient on the same day, while FQHCs are paid on a prospective payment system. The reimbursement methodologies utilized by Medicare for RHCs and FQHCs do not involve adjustments to the payment amount on an individual patient basis for services furnished by the RHC or FQHC. These payment methodologies are in contrast to payment made to physicians under the MPFS, which is generally on a fee-for-service basis. Namely, physicians receive separate reimbursement for individual services furnished to a particular patient. Individual practitioners who furnish services at RHCs and FQHCs cannot bill under the MPFS while working at the RHC or FQHC.

To address concerns about the adequacy of payment for care management services furnished by RHCs and FQHCs, CMS established separate payment for care coordination services beginning January 1, 2016. CMS established HCPCS code G0511, which is intended to be used by RHCs and FQHCs when these providers furnish chronic care management or behavioral health integration services. The reimbursement rate for G0511 has historically been set based on the average of the national non-facility rates for chronic care management and general behavioral health integration codes.

Proposed Reimbursement for Remote Monitoring Services Furnished in RHCs and FQHCs

As noted, RPM and RTM services are not currently separately reimbursable when these services are furnished by healthcare providers in RHCs and FQHCs. When these services are furnished incident to an RHC or FQHC visit, payment is currently included in the established payment rates for RHCs and FQHCs.

The availability of Medicare reimbursement for remote monitoring services under the MPFS has led to an explosion of interest in furnishing these services. As remote monitoring has become more

widely available, RHCs and FQHCs have expressed interest in furnishing RTM and RPM services and have submitted requests to CMS to expand reimbursement for these remote monitoring services. Stakeholders have pushed for CMS to establish new G-codes to reimburse RHCs and FQHCs for RPM and RTM services.

In response to these concerns, CMS proposes to include RPM and RTM services in the payment for HCPCS code G0511 when these services are furnished by RHCs and FQHCs. This is intended to reflect the additional resources necessary for the unique components of these services. If this provision is finalized, RPM and RTM services furnished by RHCs or FQHCs could be billed utilizing HCPCS code G0511 on an RHC or FQHC claim for dates of service on or after January 1, 2024.

Under this proposal, RPM and RTM services furnished by RHCs and FQHCs must be medically reasonable and necessary, must meet all requirements for the codes under the MPFS, and may not be duplicative of services paid to RHCs and FQHCs under the general care management code for an episode of care in a given calendar month.

Modification to RHC and FQHC Payment Calculation for Care Management Services

While CMS proposes to provide RHCs reimbursement for RPM and RTM services, CMS declined to establish new G-codes that would correspond directly to RPM and RTM services. CMS instead proposes to use an existing HCPCS code, G0511, to compensate RHCs and FQHCs for RPM and RTM services. CMS also proposes adding two categories of care management services (principal illness navigation services and community health integration services) to the services eligible to be reimbursed under G0511.

Because of the proposed changes in the services that would be reimbursable to RHCs and FQHCs under G0511, CMS also proposes to modify the current reimbursement for HCPCS code G0511 to better reflect the codes that would be billable under this bundled code. Reimbursement for HCPCS code G0511 is currently based on an average of the national non-facility payment rate under the MPFS for each service that is included in this code. This average is based on the national non-facility MPFS payment rates for CPT codes 99490, 99487, 99484, 99491, 99424 and 99426. Add-on HCPCS codes are not currently included in the reimbursement methodology. Accordingly, with CMS's proposal to rely on this code for additional care management services that have lower payment rates, the effective reimbursement rate for this code would be reduced. CMS is concerned the current reimbursement rate methodology for G0511 does not accurately reflect the costs associated with furnishing different care management services.

To address this concern regarding the adequacy of reimbursement under G0511, CMS proposes to modify the reimbursement methodology for G0511 to rely instead on a weighted average of the utilization of services that together comprise G0511 (or, would be included in G0511). CMS plans to use the most recently available utilization data from services paid in physician office setting as a proxy, with the reimbursement rate based on the non-facility rate for the services under the MPFS. This reimbursement methodology would be based on utilization data from CY 2021 under the MPFS.

CMS proposes to take the weighted average of the base code and add-on code pairs, together with the individual base codes for all of the services that comprise HCPCS code G0511, to calculate the payment rate for the general care management services furnished in RHCs and FQHCs on or after January 1, 2024. This weighted average would be based on the national non-facility MPFS payment rates for the CPT codes (including base code and add-on code pairs) noted below:

CPT Code	2021 Non-Facility MPFS Utilization	Weighted Average
99454	931,411	46,710,262
99457	492,286	24,023,557
99457+99458	398,209	35,221,586
99474	1,581	24,110
99091	55,435	3,005,686
98976	93,141	4,671,028
98977	93,141	4,671,028
98980	14,112	698,243
98980+98981	119,463	10,647,711
99424	13,719	1,115,766
99424+99425	4,573	638,482
99426	28,858	1,770,134
99426+99427	9,619	1,046,382
99484	151,808	6,533,816
99487	26,441	3,521,412
99487+99489	229,004	46,641,245
99490	3,436,429	215,429,734
99490+99439	802,656	88,396,505
99491	29,665	2,523,322
99491+99437	118,661	17,210,562

CMS notes in the proposed rule that an alternative methodology would involve using the national average of the top three services that comprise HCPCS code G0511, but CMS did not receive any comments on the proposed compensation methodology.

RTM UPDATES FOR PHYSICAL AND OCCUPATIONAL THERAPISTS

RTM refers to the use of medical devices to monitor a patient's health or response to treatment using non-physiological data. RTM can be used to monitor things like medication adherence, response to therapy, musculoskeletal activity and respiratory activity. RTM codes, as non-evaluation-and-management services, are eligible to be furnished and billed by a broader variety of licensed clinicians than, for example, RPM services.

Physical therapists (PTs) and occupational therapists (OTs) are eligible to both provide and bill for RTM services. However, under existing Medicare coverage and payment requirements, all occupational and physical therapy services furnished in private practice must be performed by, or under the direct supervision of, the occupational or physical therapist. This limits the ability of PTs and OTs in private practice to bill for RTM services furnished by physical therapist assistants (PTAs) or occupational therapist assistants (OTAs) who may furnish these services under the supervision of the PT or OT. "Direct supervision" requires that the billing provider be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. In contrast, "general supervision" is a lower level of supervision that requires the service to be furnished under the billing provider's overall direction and control but does not require the billing provider's presence during the service.

CMS proposes to modify existing regulations for PTs and OTs to permit RTM to be furnished under general supervision when the services are furnished by PTAs or OTAs.

Under existing regulations, therapists in private practice are required to enroll and meet additional requirements for participation in Medicare. OTs and PTs that are not enrolled in Medicare or working as an employee of a Medicare-enrolled OT or PT do not meet these general requirements. Accordingly, CMS proposes to clarify that any PTs or OTs who are not enrolled in Medicare must furnish services under the direct supervision of a Medicare-enrolled PT or OT. The proposed general supervision standard for RTM services would apply only to PTAs and OTAs furnishing services under an enrolled PT or OT, and would not include services furnished by an unenrolled PT or OT.

CMS specifically seeks comment on how this policy currently functions with PTs and OTs who are not enrolled, as well as CMS's proposal to maintain its policy requiring direct supervision for unenrolled PTs and OTs.

KEY TAKEAWAYS

Remote monitoring has become a key service offering over the past several years. CMS has

been broadly supportive of this expansion by providing separate payment for these services and providing guidance on appropriate coding and billing for these services. However, CMS is also attempting to keep up with a rapidly growing and evolving area of clinical practice. In the 2024 MPFS proposed rule, CMS both provides additional reimbursement for certain rural healthcare providers and also reiterates existing guidelines for the appropriate billing and use of remote monitoring services.

Given the continued development and implementation of CMS policies for remote monitoring services and the increasing utilization of these codes by a wide variety of clinical specialties, affected stakeholders should monitor developments in CMS coverage and payment policies closely. CMS seeks input from healthcare providers and stakeholders regarding how remote monitoring and other digital technologies are currently being used in clinical practice and on the specific topics noted above. It is also clear that CMS is actively considering the need for further guidance, education, program instructions or rulemaking regarding remote monitoring services.

Comments and responses to the requests for information included in the proposed rule can be submitted to CMS electronically at http://www.regulations.gov or by mail no later than September 11, 2023.

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