E. Care Management Services and Remote Physiologic Monitoring Services

1. Background

In recent years, we have updated PFS policies to improve payment for care management and coordination. Working with the CPT Editorial Panel and other clinicians, we have expanded the suite of codes describing these services. New CPT codes were created that describe services that involve direct patient contact (for some services, in-person) or do not involve direct patient contact; represent a single encounter, monthly service, or both; are timed services; address specific conditions; and represent the work of the billing practitioner, auxiliary personnel (specifically, clinical staff), or both (*see* Table 13). In this proposed rule for CY 2021, we continue our work to improve payment for care management services through proposed code refinements related to remote physiologic monitoring (RPM), transitional care management (TCM), and psychiatric collaborative care model (CoCM) services.

TABLE 13: Summary of Care Management Codes

Service	Summary
Care Plan Oversight (CPO) (also referred to as Home Health Supervision, Hospice Supervision) (HCPCS codes G0181, G0182)	Supervision of home health, hospice, per month
ESRD Monthly Services (CPT codes 90951-70)	ESRD management, with and without face-to-face visits, by age, per month
Transitional Care Management (TCM) (adopted in 2013) (CPT codes 99495, 99496)	Management of transition from acute care or certain outpatient stays to a community setting, with face-to-face visit, once per patient within 30 days post-discharge
Chronic Care Management (CCM) (adopted in 2015, 2017, 2019, 2020, 2021) (CPT codes 99487, 99489, 99490, 99491, HCPCS code G2058 (99XXX proposed 2021 replacement)	Management of all care for patients with two or more serious chronic conditions, timed, per month
Advance Care Planning (ACP) (adopted in 2016) (CPT codes 99497, 99498)	Counseling/discussing advance directives, face-to-face, timed
Behavioral Health Integration (BHI) (adopted in 2017) (CPT codes 99484, 99492, 99493, 99494, HCPCS code GCOL1 proposed for 2021)	Management of behavioral health conditions(s), timed, per month
Cognitive Impairment Assessment and Care Planning (adopted in 2017) (CPT code 99483)	Assessment and care planning of cognitive impairment, face-to-face visit
Prolonged Evaluation & Management (E/M) Without Direct Patient Contact (adopted in 2017) (CPT codes 99358, 99359)	Prolonged non-face-to-face E/M work related to a face-to-face visit (other than office/outpatient visits beginning in 2021), timed
Prolonged Office/Outpatient E/M Visit (adopted for 2021) (CPT code 99XXX)	Prolonged face-to-face and/or non-face to face E/M work related to an office/outpatient E/M visit, timed
Remote Physiologic Monitoring Treatment Management Services (RPM) (adopted in 2020) (CPT codes 99457, 99458)	Development and management of a plan of treatment based upon patient physiologic data
Interprofessional Consultation (adopted in 2019) (CPT codes 99446, 99447, 99448, 99449, 99451, 99452)	Inter-practitioner consultation
Principal Care Management (adopted in 2020) (HCPCS codes G2064, G2065)	Management of a single, high risk disease

2. Digitally Stored Data Services/Remote Physiologic Monitoring/Treatment Management Services (RPM)

RPM involves 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. In recent years, we have finalized payment for seven CPT codes in the RPM code family. Five of the seven codes have been the focus of frequent questions from stakeholders.

In response to proposals in the CY 2019 PFS proposed rule (83 FR 35771) and the CY

2020 PFS proposed rule (84 FR 40555 through 40556), stakeholders requested that we clarify how we interpret aspects of the RPM code descriptors for CPT codes 99453, 99454, 99091, and 99457. Commenters asked us, for example, to identify who can furnish RPM services, what kinds of medical devices can be used to collect data, how data should be collected, and how "interactive communication" is defined. We stated in the CY 2020 PFS final rule (84 FR 62697) that we would provide guidance in the future about the codes. For CY 2021, we are clarifying how we read CPT code descriptors and instructions associated with CPT codes 99453, 99454, 99091, and 99457 (and the add-on code, CPT code 99458) and their use to describe remote monitoring of physiologic parameters of a patient's health.

The RPM process begins with two practice expense (PE) only codes, CPT codes 99453 and 99454, finalized in the CY 2019 PFS final rule (83 FR 39574 through 39576). As PE only codes they are valued to include clinical staff time, supplies, and equipment, including the medical device for the typical case of remote monitoring. CPT code 99453 (*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*) is valued to reflect clinical staff time that includes instructing a patient and/or caregiver about using one or more medical devices. CPT code 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*) is valued to include the medical device or devices supplied to the patient and the programming of the medical device for repeated monitoring. We reviewed the PE inputs for CPT code 99454 for purposes of this proposal, and are clarifying that the medical device or devices that are supplied to the patient and used to collect physiologic data are considered equipment and as such are direct PE inputs for the code.

Review of CPT prefatory language (CPT® 2020 Professional Codebook (hereafter, CPT Codebook), p.42) provides additional information about the two PE only codes. For example, the CPT prefatory language indicates that monitoring must occur over at least 16 days of a 30-day period in order for CPT codes 99453 and 99454 to be billed. Additionally, these two codes are not to be reported for a patient more than once during a 30-day period. This language suggests that even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed only once per patient per 30-day period and only when at least 16 days of data have been collected. We also note that CPT 99453 can be billed only once per episode of care where an episode of care is defined as "beginning when the remote physiologic monitoring service is initiated and ends with attainment of targeted treatment goals" (CPT Codebook, p. 42).

Other stakeholder inquiries about CPT codes 99453 and 99454 focus upon the kinds of medical devices that can be used to collect the patient's physiologic data. Prefatory language in the CPT Codebook states that "the device must be a medical device as defined by the FDA." CPT simply specifies that the device must meet the FDA's definition of a medical device as described in section 201(h) of the Federal, Food, Drug and Cosmetic Act (FFDCA). We have found no language in the CPT Codebook indicating that a medical device must be FDA cleared as some stakeholders have suggested although such clearance may be appropriate. Nor have we found information that suggests a medical device must be prescribed by a physician, although this could be possible depending upon the medical device. Beyond acknowledging the CPT specification that the medical device supplied for CPT code 99454 must meet the FDA definition of a medical device, we are clarifying that the medical device should digitally (that is, automatically) upload patient physiologic data (that is, data are not patient self-recorded and/or

self-reported). We note also that use of the medical device or devices that digitally collect and transmit a patient's physiologic data must, as usual for most Medicare covered services, be reasonable and necessary for the diagnosis or treatment of the patient's illness or injury or to improve the functioning of a malformed body member. Further, the device must be used to collect and transmit reliable and valid physiologic data that allow understanding of a patient's health status to develop and manage a plan of treatment.

The CPT Codebook lists the RPM codes under the main heading Evaluation and Management (E/M). We are clarifying that as E/M codes, CPT codes 99453, 99454, 99091, 99457, and 99458, can be ordered and billed only by physicians or nonphysician practitioners (NPPs) who are eligible to bill Medicare for E/M services.

Although we initially described RPM services in the CY 2019 PFS final rule (83 FR 35771) as services furnished to patients with chronic conditions, we are also clarifying that practitioners may furnish these services to remotely collect and analyze physiologic data from patients with acute conditions, as well as from patients with chronic conditions.

After the 30-day data collection period for CPT codes 99453 and 99454, the physiologic data that are collected and transmitted are analyzed and interpreted by the physician or practitioner as described by CPT code 99091, a code that includes only professional work, that is, there are no direct PE inputs. We finalized payment for CPT code 99091 (*Collection and interpretation of physiologic data digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation requiring a minimum of 30 minutes of time, each 30 days*) in the CY 2018 PFS final rule (82 FR 59473). The valuation for CPT code 99091 includes a total time of 40 minutes of physician or nonphysician practitioner work broken down as follows: 5

minutes of preservice work (for example, chart review); 30 minutes of intra-service work (for example, data analysis and interpretation, report based upon the physiologic data, as well as a possible phone call to the patient); and 5 minutes of post-service work (that is, chart documentation). We note that stakeholders have expressed confusion about the specification in the code descriptor for CPT code 99091 that the service is furnished by a "physician or other qualified health care professional, qualified by education, training, licensure/regulation." The phrase "physician or other qualified healthcare professional" is defined by CPT as, "an individual who is qualified by education, training, licensure/regulation (when applicable) and facility privileging (when applicable) who performs a professional service within his/her scope of practice and independently reports that professional service. These professionals are distinct from "clinical staff … [which refers to] a person who works under the supervision of a physician or other qualified healthcare professional and who is allowed by law, regulation, and facility policy to perform or assist in the performance of a specified professional service but does not individually report that professional service."[1] Accordingly, when referring to a particular service described by a CPT code for Medicare purposes, a physician or other qualified healthcare professional is an individual whose scope of practice and Medicare benefit category includes the service and who is authorized to independently bill Medicare for the service. See our previous discussion of this in the CY 2016 PFS final rule at 80 FR 70957. Medicare also covers and makes payment for certain services performed by auxiliary personnel (which includes clinical staff) "incident to" the professional services of the billing practitioner. Our regulation at § 410.26(a) defines auxiliary personnel (a term that includes clinical staff) and delineates the conditions for payment for "incident to" services.

[1] CPT Codebook, p.xiii.

After analyzing and interpreting a patient's remotely collected physiologic data, the next step in the process of RPM is the development of a treatment plan that is informed by the analysis and interpretation of the patient's data. It is at this point that the physician or nonphysician practitioner develops a treatment plan with the patient and/or caregiver (that is, patient-centered care) and then manages the plan until the targeted goals of the treatment plan are attained, which signals the end of the episode of care. CPT code 99457 (*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; first 20 minutes*) and its add-on code, CPT code 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; each additional 20 minutes*) describe the treatment and management services associated with RPM. Medicare stakeholders have requested that we clarify aspects of these two codes. The two most frequently asked questions include, "Who can furnish the services described by CPT codes 99457 and 99458?" and "What does it mean to have an 'interactive communication' with a patient?"

We addressed who can furnish CPT codes 99457 and 99458 in the CY 2020 PFS final rule (84 FR 62697 through 62698) when we designated both codes as care management services. We explained that, like other care management services, CPT codes 99457 and 99458 can be furnished by clinical staff under the general supervision of the physician or NPP. We note that RPM services are not considered to be diagnostic tests; that is, they cannot be furnished and billed by an Independent Diagnostic Testing Facility on the order of a physician or NPP.

The services described by CPT codes 99457 and 99458 are services that are typically

furnished remotely using communications technologies that allow "interactive communication," which we read as real-time interaction, between a patient and the physician, nonphysician practitioner, or clinical staff who provide the services. Stakeholders have requested that we define "interactive communication" as used in the code descriptors for CPT codes 99457 and 99458. We see this remote, non-face-to-face exchange as being similar to the exchange that occurs in providing services described by HCPCS code G2012, *Brief Communication Technology Based Service*, which we finalized in the CY 2019 final rule (83 FR 59483 through 59486). Thus, we are clarifying that "interactive communication" for purposes of CPT codes 99457 and 99458 involves, at a minimum, a real-time synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of data transmission. As indicated in the code descriptor for CPT code 99457, the interactive communication must total at least 20 minutes of interactive time with the patient over the course of a calendar month for CPT code 99457 to be reported. Each additional 20 minutes of interactive communication between the patient and the physician/nonphysician practitioner/clinical staff is reported using CPT code 99458. The CPT Codebook states that unless there are code- or code-range specific instructions, parenthetical instructions, or code descriptors to the contrary, time is considered to be the "face-to-face" time with the patient or patient's caregiver/medical decision-maker. See the CPT Codebook, page xvii, as well as pages 10, 13, and 16 for more information about measuring time. Where, as here, the services are not typically furnished in person with the patient, we interpret time in the code descriptor to mean the time spent in direct, real-time interactive communication with the patient.

Lastly, we are proposing to establish as permanent policy two of the changes we made on an interim basis to the requirements for furnishing RPM services in response to the PHE for the

COVID-19 pandemic. (See 85 FR 19264 and 85 FR 27605 through 27606 for the interim modifications and clarifications to RPM services in response to the PHE for the COVID-19 pandemic).

Our goals during the PHE for the COVID-19 pandemic have been to reduce exposure risks to the Novel Coronavirus for practitioners and patients while also increasing access to health care services. We eliminated as many obstacles as possible to allow timely delivery of reasonable and necessary health care. We wanted patients to be able to access services quickly and without barriers. With the goals of reducing exposure and increasing access to services, we finalized that RPM services could be furnished to new patients, as well as established patients. We also finalized on an interim basis for the duration of the PHE for the COVID-19 pandemic policies to allow consent to be obtained at the time services are furnished, and by individuals providing RPM services under contract with the billing physician or practitioner; and to allow RPM codes to be billed for a minimum of 2 days of data collection over a 30-day period, rather than the required 16 days of data collection over a 30-day period as provided in the CPT code descriptors.

For CY 2021, we are proposing on a permanent basis to allow consent to be obtained at the time that RPM services are furnished. Because the CPT code descriptors do not specify that clinical staff must perform RPM services, we are also proposing to allow auxiliary personnel (which includes other individuals who are not clinical staff but are employees, or leased or contracted employees) to furnish services described by CPT codes 99453 and 99454 under the general supervision of the billing physician or practitioner.

When the PHE for the COVID-19 pandemic ends, we again will require that RPM services must be furnished only to an established patient. We believe that a physician or

practitioner who has an established relationship with a patient would likely have had an opportunity to provide a new patient E/M service. During the new patient E/M service, the physician or practitioner would have collected relevant patient history and conducted a physical exam, as appropriate. As a result, the physician or practitioner would possess information needed to understand the current medical status and needs of the patient prior to ordering RPM services to collect and analyze the patient's physiologic data and to develop a treatment plan. Additionally, and in keeping with the CPT prefatory language for CPT codes 99453 and 99454, when the PHE for the COVID-19 pandemic ends, we will once again require that 16 days of data be collected within 30 days to meet the requirements to bill CPT codes 99453 and 99454.

Finally, in response to the May 19, 2020 Executive Order 13924, "Regulatory Relief To Support Economic Recovery," (85 FR 31353 through 31356), we are seeking comment from the medical community and other members of the public on whether the current RPM coding accurately and adequately describes the full range of clinical scenarios where RPM services may be of benefit to patients. For example, CPT codes 99453 and 99454 currently require use of a medical device (as defined by the FDA) that digitally collects and transmits 16 or more days of data every 30 days in order for the codes to be billed. However, some patients may not require remote monitoring for 16 or more days in a 30-day period. For some patients, continuous short-term monitoring might be more appropriate. For example, a post-surgical patient who is recovering at home might benefit from remote monitoring of his or her body temperature as a means of assessing infection and managing medications or dosage. In some situations, monitoring several times throughout a day, over a period of 10 days, may be reasonable and necessary. Sixteen or more days might be unnecessary. We are asking for information that would help us to understand whether it would be beneficial to consider establishing coding and

payment rules that would allow practitioners to bill and be paid for RPM services with shorter monitoring periods. Specifically, we are interested in understanding whether one or more codes that describe a shorter duration, for example, 8 or more days of remote monitoring within 30 days, might be useful. We welcome comments including any additional information that the medical community and other members of the public believe may provide further clarification on how RPM services are used in clinical practice, and how they might be coded, billed and valued under the Medicare PFS.