We understand that Sargas Pharmaceutical Adherence & Compliance International (SPAC International, SARGAS, or SPAC) contracts with physician practices to furnish certain care management services for qualifying Medicare beneficiaries using its ONC HIT certified Sargas hru? Chronic Care Management Cloud® dba hru2day platform. Under these contracts, SPAC is required to perform these services in a manner which permits the practice to bill Medicare for chronic care management (CCM), principal care management (PCM) services, and/or Remote Physiologic Monitoring (RPM) provided the practice itself meets specific Medicare billing requirements.

SPAC also contracts with practices to furnish some of these beneficiaries with certain devices and related data transmission services to permit the practice to bill for the technical components of remote physiologic monitoring (specifically, CPT 99453 and 99454). SPAC furnishes the monitoring data to the practice to inform the beneficiary's ongoing treatment. Also, for those beneficiaries for whom SPAC provides care management services, SPAC care managers review and refer to this data in providing those services.[1]

SPAC has engaged PYA to review its internal processes and identify opportunities for improvement. Specifically, we have focused on whether SPAC can demonstrate its compliance with applicable Medicare billing rules to the practices with which it contracts and to any third-party auditor reviewing claims submitted by such a practice.

The Centers for Medicare & Medicaid Services (CMS) has recognized that a "billing physician (or other appropriate practitioner) may arrange to have CCM services provided by clinical staff external to the practice (for example, in a case management company) if all of the "incident to" and other rules for billing CCM to the [Medicare Physician Fee Schedule] are met."[2] The following chart delineates the respective responsibilities of a practice and its care management vendor to ensure compliance with Medicare billing rules for CCM and PCM. For purposes of our review, we have focused on those items identified as Vendor Responsibilities.[3]

[1] We do not address remote treatment management services (CPT 99457 and 99458) as the 2022 increase in Medicare reimbursement for CCM and PCM eliminate the incentive to provide these services. Instead, we assume CCM or PCM services will be furnished for those beneficiaries for whom monitoring is performed. Nor do we address data analysis and interpretation (CPT 99091) because this service requires direct supervision by the billing practitioner, which is not possible under a third-party vendor arrangement such as the one SPAC has with its contracting practices.

[2] Center for Medicare & Medicaid Services, Frequently Asked Questions about Billing Medicare for Chronic Care Management Services (Mar. 17, 2016) available at https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/payment-chronic-care-management-services-faqs.pdf

[3] A review of SPAC's existing contracts to determine whether they appropriately delineate between SPAC's and the practice's responsibilities is beyond the scope of this engagement.

Vendor Responsibilities	Practice Responsibilities
Assist with identification of beneficiaries who may qualify for CCM/PCM services	Arrange for treating physicians to introduce CCM/PCM services to identified beneficiaries at scheduled appointments
Secure consent from and onboard those beneficiaries with written orders	Arrange for treating physicians to provide written orders for CCM/PCM services with documentation of medical necessity
Facilitate physicians' general supervision for SPAC clinical staff providing CCM services	Identify one or more physicians to provide general supervision for SPAC clinical staff providing CCM/PCM services (services billed under these physicians' NPIs)
Arrange for qualified clinical staff to develop and update individualized electronic care plan for each CCM beneficiary for review and approval by treating physician; incorporate care plan into CCM beneficiary's electronic health record	Make available to SPAC clinical staff electronic health records for CCM/PCM beneficiaries Arrange for treating physicians to review and approve draft and updated care plans in timely manner
Arrange for qualified clinical staff to provide appropriate care management services for each CCM beneficiary and to properly document those services; incorporate documentation into CCM beneficiary's electronic health record in a manner that meets best practice	
Provide enhanced opportunities for communication with CCM beneficiaries by video/telephone and asynchronous methods	
Deliver to practice on a monthly basis an accounting of CCM services furnished to beneficiaries indicating those services for	Make final decision regarding those services to be billed; submit claims and collect payment; make payment to SPAC

which Practice may submit claim for reimbursement	
	Satisfy CCM/PCM requirement for use of certified electronic health record
	Maintain and adhere to policy and procedure to ensure CCM beneficiaries can receive successive routine appointments with treating physician, understanding the treating physician may differ from the provider supervising CCM services
	Maintain and adhere to policy and procedure detailing following capabilities: (1) follow up with CCM beneficiary following ER visit; (2) provide post-discharge transitional care management services as necessary; (3) coordinate referrals to other clinicians; and (4) create and exchange timely continuity-of-care documents with other practitioners and providers.
Establish processes to identify and compile a list of resources available in the community to address social determinants of health for CCM beneficiaries (e.g., nutrition, housing, transportation); coordinate appropriate resources for CCM beneficiaries	Maintain and adhere to policy and procedure detailing capabilities to coordinate with home- and community-based clinical service providers for which physician order is required (e.g., home health and hospice, outpatient therapies, durable medical equipment); document communication with these service providers on behalf of a beneficiary in the beneficiary's medical record.
	Maintain and adhere to policy and procedure detailing how CCM beneficiaries can access Practice's practitioner/clinical staff on 24/7 basis to address acute/urgent needs in a timely manner.

The following details the Medicare billing rules for CCM and PCM services[4] and the technical components of remote physiologic monitoring (CPT 99453 and 99454) (RPM); identifies the action necessary to comply with these requirements; comments on SPAC's compliance with applicable requirements based on the information made available to PYA; and makes recommendations to enhance operations.

1. Initiating Visit/Established Patient

Rule: If the billing practitioner has not seen the beneficiary in the last 12 months (or if the beneficiary is a new patient), the practitioner must discuss CCM with the beneficiary as part of a face-to-face visit (e.g., regular office visit, annual wellness visit (AWV), or initial preventive physical exam (IPPE)), prior to billing for CCM for that beneficiary. The face-to-face visit is not a component of the CCM service, and thus may be billed separately. No initiating visit is required for the practitioner to begin billing for CCM services if he or she has seen the patient within the last 12 months.

For RPM services, a beneficiary must be an established patient to the practice of the billing practitioner.

Compliance: We understand SPAC requests from each practice with which it contracts a list of those traditional Medicare beneficiaries with two or more chronic conditions (or, in the case of a specialist practice billing for PCM, one chronic condition) who have been seen within the practice within the last 12 months SPAC uses this list exclusively to identify potential beneficiaries. Thus, the pool of potential CCM candidates is limited to traditional Medicare beneficiaries for whom a face-to-face visit has been billed within 12 months prior to initiation of CCM services. This practice also ensures compliance with the established patient requirement for RPM services.

2. Beneficiary Consent

Rule: As a precondition to billing for CCM, the billing practitioner (or qualified clinical staff under his or her general supervision) must inform the beneficiary of the following orally or in writing:

- the availability of CCM services and applicable cost sharing
- that only one physician can furnish and be paid for CCM services during a calendar month

[4] As the billing rules for CCM and PCM services are the same with a few exceptions, the following discussion refers to CCM only, except with respect to those exceptions.

- that the beneficiary has the right to discontinue CCM services at any time, effective at the end of the calendar month in which notification is made.

The beneficiary's consent to receive CCM services following the receipt of such notice. Such consent may be given verbally but it must be documented in the beneficiary's medical record.

Similarly, the practitioner must secure the beneficiary's consent to receive RPM either prior to or at the initiation of the service, including an acknowledgement that the beneficiary will be responsible for the co-payment or deductible associated with the services. Again, the consent may be given verbally but it must be documented in the beneficiary's medical record.

Compliance: We have reviewed the forms SPAC uses to enroll patients in CCM services. These forms include the required notices for purposes of consent. We understand the completed documents for each beneficiary are maintained in SPAC's ONCHIT-certified hru2day platform and available for download to the billing practitioner's EHR. .

For those beneficiaries for whom SPAC is providing RPM services in addition to CCM services, SPAC indicates the case managers obtain and document the beneficiary's separate consent for those services to avoid potential audit issues.

In obtaining consent, SPAC staff should follow the billing practitioner's existing policies regarding consent for treatment. If the beneficiary is not competent to give his or her consent for CCM and/or RPM services, the consent should be given by an individual with legal authority under applicable state law to consent to treatment on behalf of the beneficiary.

Note there is no requirement to periodically obtain an updated consent as long as the beneficiary continues to receive CCM and/or or RPM services from the billing practitioner on a regular basis.

3. Medical Necessity

Rule: To be eligible for Medicare reimbursement, an item or service must be medically necessary. This requires a determination by the ordering practitioner that the items or service is needed to diagnose or treat the beneficiary's illness, injury, condition, or disease (including symptoms). For some items or services, CMS billing rules define medical necessity by limiting coverage to beneficiaries with specified diagnoses.

For CCM, the rules requires that the beneficiary have two or more chronic conditions expected to last at least 12 months (or until the beneficiary's death) that place the beneficiary at significant risk of death, acute exacerbation/decompensation, or functional

decline. For PCM, the beneficiary must have a single chronic condition requiring stabilization following exacerbation or hospitalization.

CMS has not identified the specific circumstances in which CMS will make payment for RPM other than to indicate the monitoring should be reasonable, medically necessary, and "used to develop and manage a treatment plan related to a chronic and/or acute health illness or condition."

Compliance: CMS has not provided a definite list of conditions that qualify for CCM or PCM. However, CMS maintains a Chronic Condition Warehouse (CCW), which organizes data for approximately 60 specified chronic conditions and potentially disabling conditions. https://www2.ccwdata.org/web/guest/condition-categories. Some auditors have challenged CCM services for conditions other than those included in the CCW.

We understand some third-party auditors require a written order from the billing practitioner confirming medical necessity when care management services are furnished by a third party. These auditors have found lists of beneficiaries meeting specified criteria generated electronically from the practice's EHR or billing system insufficient for these purposes; the final decision whether CCM, PCM, and/or RPM services are medically necessary for a specific beneficiary must be made by the practitioner. We understand SPAC's platform has an area for the billing practitioner to approve the care plan. , We recommend SPAC advise practitioners to utilize this area to document medical necessity for CCM, PCM, or RPM services for a specific beneficiary.[5]

For CCM, such order would confirm the beneficiary's chronic conditions are expected to last at least 12 months (or until the beneficiary's death) that place the beneficiary at significant risk of death, acute exacerbation/decompensation, or functional decline. The order for PCM would confirm the single chronic condition requires stabilization following exacerbation or hospitalization. For RPM, the order would identify the specific condition to be monitored and the parameters for such monitoring (e.g., daily blood pressure readings).

CMS does not require the beneficiary be re-evaluated at certain intervals to determine whether CCM services remain medically necessary. However, an auditor still may question the provision of CCM services over an extended period absent some determination that the services continue to benefit the patient. Thus, SPAC should consider recommending "renewal" orders for CCM services (e.g., on an annual basis). The same is true with respect to RPM services.

[5] We recognize the practice is ultimately responsible for ensuring all services for which it submits claims to Medicare are medically necessary. Our recommendations regarding written orders for CCM, PCM, and RPM services are intended to facilitate strong working relationships with the practices for which SPAC provides services. In the event a practice is subject to repayment for services furnished by SPAC, the practice is likely to argue SPAC is responsible for failing to establish appropriate processes for compliance with billing rules.

For PCM services, the duration of services is limited to the time necessary to stabilize the beneficiary's condition. Ideally, the treating practitioner's order should identify the period of time over which services should continue, measured by time or the occurrence of a specific event (i.e., the beneficiary achieves a certain milestone). Absent such specificity in the order, the billing practitioner should be consulted to validate the continued need for services. Such confirmation should be documented. The frequency of such consultations should be based on the beneficiary's condition, e.g., if the beneficiary's condition has remained stable over a period of time, it may be appropriate to inquire with the billing practitioner regarding the need for continued services.

4. Specified Capabilities

As a condition for billing for CCM, the billing practitioner (or the physician practice under which the billing practitioner submits claims for CCM) must maintain the following four capabilities, either directly or under contract. The submission of a claim for CCM is, in effect, an attestation to each of these capabilities.

Documentation of individual CCM services does not have to include documentation of compliance with these requirements. However, the billing practitioner should adopt and adhere to a formal policy and procedure demonstrating compliance.

As noted below, SPAC may assume responsibility for compliance with some specific requirements. In those cases, such responsibilities should be delineated in the contract between SPAC and the practice, making clear that the practice is responsible for compliance with these capabilities except to the extent SPAC has assumed responsibility.[6] SPAC should then have a formal policy and procedure detailing its compliance efforts with respect to each requirement for which it has accepted responsibility in its contracts with providers.

(a) Use of Certified Electronic Health Record

Rule: The billing practitioner is not required to be a meaningful user of a certified EHR technology, but is required to use "CCM certified technology" to meet the following core technology capabilities:

1. Structured recording of demographics, problems, medications, and medication allergies, all consistent with 45 CFR 170.314(a) (3)-(7).

[6] Again, this recommendation is based on the assumption a practice would look to SPAC for relief in the event of an audit in which claims were disallowed due to non-compliance with billing rules.

2. Creation of summary care record consistent with 45 CFR 170.314(e)(2). The practitioner must be able to transmit the summary care record electronically for purposes of care coordination, although CMS does not specify acceptable methods of transmission.

Compliance: We understand SPAC's hru2day platform is ONCHIT-certified and that this platform also makes the patient care plan available to the patient and the patient's providers via Sargas hru? Cloud and individual login for each to access this updated information in real time. Also, we understand SPAC's written agreement with the billing practitioner includes a representation by the billing practitioner that it is a meaningful user of a certified EHR technology.

(b) Access to Care

Rule: The billing practitioner must have the capability to:

1. Provide a means for the beneficiary to access a member of the care team on a 24/7 basis to address acute/urgent needs in a timely manner.

2. Ensure the beneficiary can receive successive routine appointments with a designated practitioner or member of the care team.

3. Provide enhanced opportunities for beneficiary-provider (or caregiver-provider) to communicate by telephone and asynchronous consultation methods (e.g., secure messaging).

Compliance: We understand SPAC provides beneficiaries with 24/7 access to a member of the care team through its Patient CARE Hotline (844-926-CARE) and makes secure messaging available to beneficiaries through its hru? Cloud platform. We also understand SPAC's written agreement with the billing practitioner includes a representation that the billing practitioner is responsible for ensuring the beneficiary can receive successful routine appointments with a designated practitioner or member of the care team.

(c) Transitions of Care

Rule: The billing practitioner must have the capability to:

1. Follow up with the beneficiary after an ER visit.

2. Provide post-discharge transitional care management services as necessary.

3. Coordinate referrals to other clinicians.

4. Create and exchange timely continuity-of-care documents with other practitioners and providers.

Compliance: We understand SPAC's written agreement with the billing practitioner includes a representation by the billing practitioner regarding compliance with the transitions of care requirements. SPAC represents in the agreement that it will assist the practitioner with follow-up from emergency department visits and facility discharges.

(d) Care Coordination

Rule: The billing practitioner must have the capability to coordinate with home- and community-based clinical service providers (including home health and hospice, outpatient therapies, durable medical equipment, transportation services, and nutrition services) to meet the beneficiary's psychosocial needs and functional deficits.

The practitioner's communication with these service providers must be documented in the beneficiary's medical record.

Compliance: We understand SPAC's written agreement with the billing practitioner includes a representation by the billing practitioner regarding compliance with the care coordination requirements for those services for which a physician order is required (e.g., home health and hospice, outpatient therapies, durable medical equipment).

Working with the billing practitioner, SPAC indicates it can establish processes to identify and compile a list of resources available in the community to address social determinants of health for Medicare beneficiaries. Coordination of such resources (e.g., transportation, nutrition, assistance with securing

medications)can also be stored in the hru? Cloud portal and areincluded as part of the care management services furnished by clinical staff.

5. Care Plan

Rule: The billing practitioner must develop and regularly update (at least annually) an electronic patient-centered care plan based on a physical, mental, cognitive, psychosocial, functional, and environmental (re)assessment of the beneficiary's needs. For CCM, the plan should address all health issues (not just chronic conditions) and be congruent with the beneficiary's choices and values. For PCM, the plan may be limited to a single condition necessitating care management services.

CMS requires the care plan be accessible in the following manner:

- A copy of the care plan (paper or electronic) must be offered to the beneficiary, and such offer must be documented in the beneficiary's medical record.
- The care plan must be accessible to the care team on a 24/7 basis.
- The billing practitioner must have the capability to share the care plan electronically (other than facsimile) with other providers caring for the beneficiary.

CMS guidance states a care plan should include the following:

- List of current practitioners and suppliers that are regularly involved in providing medical care to the beneficiary.
- Assessment of the beneficiary's functional status related to chronic health conditions.
- Assessment of whether the beneficiary suffers from any cognitive limitations or behavioral health conditions that could impair self-management.
- Assessment of the beneficiary's preventive healthcare needs.
- Requirement for periodic review and revision.

The guidance also identifies the following items as 'typically' included in a care plan (but not specifically required in each plan):

- Problem list with expected outcome and prognosis and measurable treatment goals.

- Symptom management and planned interventions (including all recommended preventive care services).
- Monitoring to be performed.
- Community/social services to be accessed.
- Plan for care coordination with other providers.
- Medication management (including list of current medications and allergies; reconciliation with review of adherence and potential interactions; oversight of patient self-management).
- Responsible individual for each intervention.

Compliance: SPAC furnished PYA with examples of patient care plans maintained on the platform for patients receiving CCM services. These examples included the key elements identified by CMS.

The written agreement between SPAC and the billing practitioner places the responsibility for generation and sharing of the care plan with the billing practitioner. The agreement states SPAC will provide information to be inputted into the care plan and that SPAC will make the care plan available to the beneficiary through its portal.
The documentation provided to PYA by SPAC did not include a detailed description of the process for development and review of the care plan and the parties' respective responsibilities. PYA recommends this process be formalized and reduced to writing to demonstrate compliance with these billing rules.

As we understand SPAC's operations, the assigned case manager is responsible for drafting the initial care plan. This should be accomplished using standard templates approved by the practice, compiling information from the beneficiary's medical record and direct communication with the beneficiary (or caregiver). The draft care plan should then be reviewed, revised, and approved by the billing practitioner. Going forward, the case manager updates the care plan to reflect changes in the beneficiary's condition, with significant changes reviewed and approved by the practitioner. SPAC's written agreement with the practice should include the practitioner's duties with respect to care plan review, revision, and approval.

The time spent developing and reviewing the care plan can be counted towards the minutes required to bill CCM or PCM, unless it is included as content to another service. For example, the time spent with a beneficiary completing a medical history or reviewing medications as part of an office visit cannot be counted. By contrast, the time spent by

the care manager reviewing information in the beneficiary's medical records for purposes of developing the care plan can be counted.

If the billing practitioner himself or herself spends 30 minutes in a given month reviewing, revising, and approving a beneficiary's care plan, such time may be billed under CPT 99491 (for CCM) or CPT 99424 (for PCM). (For 60 minutes or more, the appropriate add-on code may be billed.) If the billing practitioner spends less than 30 minutes, his or her time spent may be added to the time spent by clinical staff billed under CPT 99490 or CPT 99439. Again, no time should be counted if it is included as content to another service (e.g., prolonged E/M services).

Regarding SPAC's access to beneficiaries' clinical information for care plan development and practices' access to care plans, SPAC should establish processes and procedures for accessing practices' EHRs for those beneficiaries for whom SPAC is providing care management services (including appropriate access restrictions/security measures). SPAC indicates it works under a BAA its contracted practices and hereby has access to the patient record via their respective EHR.

6. Care Management Services – Clinical Staff

Rule: Care management services may be furnished by clinical staff under the general supervision of the billing practitioner. General supervision does not require the billing practitioner to review each service furnished by clinical staff; instead, the billing practitioner is responsible for determining the assigned staff person has adequate and appropriate training, experience, and expertise to furnish care management services. Also, the supervising physician must be available to address specific patient-related questions from the case managers.

Compliance: The documentation provided to PYA by SPAC did not specifically address how general supervision of clinical staff is accomplished. We recommend SPAC develop and implement a written policy and procedure regarding billing practitioners' supervision of case managers, including documentation of billing physician's review and approval of each care manager's qualifications, experience, and training relating to CCM and the method(s) by which physician and case managers can communicate on ongoing basis, identification of specific matters to be communicated to physician.

We understand SPAC makes available information regarding its case managers to the billing practitioner via the platform (including job description, credentials, and training materials). In addition, SPAC should make available its process for verifying qualifications (including licensure) and experience for each case manager; documentation of regular review of OIG exclusions list for all then-current case managers; documentation of completed training for each care manager prior to commencing patient communications; and documentation of ongoing training activities (e.g., copies of notifications or reminders circulated to case managers relating to provision of care management

services). According to SPAC, Sargas HRU? Cloud maintains under the case manager's individual master file all the certifications, resume, credentials, training and licensure for each of its case managers. Each case manager is assigned unique initials that are logged for each patient interaction and work logs that add up to 20 minutes. In the event of an audit, documentation can be provided for each patient including which case manager completed the service for each month.

7. Care Management Services – Time Requirements

Rule: The following table summarizes the time requirements for the relevant CCM and PCM codes:

CCM	**CPT 99490** Initial 20 minutes, clinical staff	**CPT 99439** Subsequent 20 minutes, clinical staff
PCM	**CPT 99426** Initial 30 minutes, clinical staff	**CPT 99427** Subsequent 30 minutes, clinical staff
RHC/FQHC Care Management Services[7]	**G0511** Minimum of 20 minutes, clinical staff	No add-on code

CMS has specifically identified the following services that can be counted towards the requisite minutes of non-face-to-face services; this is not an exhaustive list, and not all of these services must be provided to any one beneficiary:

- Systematic assessment or reassessment of the beneficiary's medical, functional, and psychosocial needs.
- System-based approaches to ensure timely receipt of all recommended preventive care services.
- Provision of education and response to questions from the beneficiary, family, guardian, and/or caregiver.

[7] An RHC or FQHC can bill for a service that satisfies the requirements for either CCM or PCM under G0511.

- Medication management, including:
  - Medication reconciliation.
  - Review of medication adherence and potential interactions.
  - Oversight of patient self-management of medications.

- Support of care transitions between and among healthcare provider settings, including:
  - Referrals to other clinicians.
  - Follow-up after emergency room visit.
  - Follow-up after discharge from hospitals, skilled nursing facilities, or other healthcare facilities.

- Identification of the need for and communication coordination with home- and community-based service providers required to support the patient's psychosocial needs and functional deficits.

- Development, maintenance, and communication regarding the care plan.

- Collection of health outcomes data and registry documentation.

- Review and interpretation of data from remote monitoring.

Other tasks which are purely administrative and require no clinical training or background (e.g., transcription, sending automated messages) do not qualify as care management services. Time spent performing such tasks cannot be counted as care management time.

Generally speaking, only time spent on non-face-to-face services may be included. However, limited face-to-face services may be included, provided they remain the exception and not the rule. Clinical staff is not required to have direct interactive communication with the beneficiary as a condition for billing for CCM services for a given month (although the exclusive use of non-interactive services may raise concerns in the event of an audit).

CMS does not specify documentation requirements for non-face-to-face care management services. To avoid any issues on audit, documentation should include the following:

- Date and amount of time spent providing non-face-to-face care management services (preferably start and stop times).

- Clinical staff furnishing the services (including credentials).

- Brief description of the services provided. Presumably descriptions will vary by patient and care plan interaction to avoid the perception of blanket copy/paste documentation.

To count the total minutes during a calendar month to determine the appropriate code(s), apply the following:

- Time spent while the beneficiary is an inpatient at a facility cannot be counted (including a post-hospital-discharge Part A SNF stay)

- Time spent by multiple individuals for the same beneficiary may be aggregated (except as noted below).

- Do not "round up."

- Do not carry forward "extra" minutes from the prior month.

- If two or more individuals are discussing a beneficiary, only one individual's time may be counted.

- If care management services are furnished on the same day the billing practitioner furnishes evaluation and management services for the beneficiary, the care management services must be separate and distinct from the E/M services for the time to be counted. (We expect this issue will not arise, given the case managers are not present in the practice.)

Regarding claim submission, the billing practice should apply the following rules:

- The claims should be submitted under the NPI of the practitioner providing general supervision of care management staff.

- A claim for care management services may be submitted each month as soon as the required minimum number of minutes of non-face-to-face care management services have been provided. However, if an add-on code may apply, claims should not be filed until the billing requirements of the add-on code are met since the codes must be billed together.

- The date of service for care management services is the day on which the minimum minute requirement is satisfied or any day thereafter through the end of the calendar month. If the beneficiary dies during the month, the claim for care management services will be paid only if the date of service is prior to the date of death.

- The place of service for care management services is the location at which he or she would furnish a face-to-face office visit with the beneficiary.

- A practitioner who bills for CCM services cannot bill for the following services for the same beneficiary during the same calendar month:

    - Transitional care management (TCM) (CPT 99495 and 99496) (except as provided below)
    - Home healthcare supervision (HCPCS G0181)
    - Hospice care supervision (HCPCS G0182)
    - End-stage renal disease services (CPT 90951-90970)

- TCM and CCM/PCM may be billed by the same practitioner in the same calendar month for the same beneficiary if the 30-day post-discharge service period for TCM concludes prior to the end of that calendar month, and the minimum number of minutes of care management services are furnished between that time and the end of that month.

Having reviewed the SARGAS HRU? CLOUD's portal, it appears to be a well-designed documentation and time-tracking tool for CCM services. SPAC should develop a written policy and procedure and related training materials for clinical staff regarding appropriate care management activities for which time can be recorded.

We also recommend SPAC communicate to the practices the claim submission requirements for CCM. For example, SPAC's current invoices identifying the beneficiaries for whom SPAC provided care management services and the total number of minutes performed SARGAS HRU? CLOUD confirms that the practices are using the last day of the month as the date of service.

7. RPM Services – Initiation and Monthly Data Transmission

Rule: CPT 99453 is used to report beneficiary education on use of the device(s). According to CPT Guidelines, CPT 99453 can be billed only once per episode of care (defined as "beginning when the remote monitoring physiologic service is initiated and ends with attainment of targeted treatment goals") even if multiple devices are provided to the beneficiary.

CPT Guidelines further state that CPT 99453 should not be reported "if monitoring is less than 16 days." Thus, if a beneficiary receives and is educated on the device(s), but data is not collected by the device for a minimum of 16 days in a 30-day period, one could not bill for CPT 99453.

CPT 99454 is used to report the provision and programming of the device(s) for daily recording or programmed alert transmissions over a 30-day period, provided data is collected for at least 16 days during the 30-day period. CPT 99454 can be billed only once per 30-day period, even if multiple devices are utilized.

CPT 99454 can be billed for a 30-day period only if at least 16 days of data is collected during the period. For example, if monitoring services commenced for a beneficiary on July 1 and data was recorded each day through September 12, one would bill CPT 99453 in July and CPT 99454 in July and August (but not September).

CMS will not pay more than one practitioner for CPT 99453 for an episode of care or CPT 99454 for a 30-day period, even if each practitioner is arguably furnishing a distinct service. According to CMS, "[t]he medically necessary services associated with all the medical devices for a single patient 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." CMS, however, offers no direction regarding the resolution of claims submitted by multiple practitioners for the same beneficiary for the same time period.

Regarding the device requirements for CPT 99453 and 99454, CMS has specified that any such device must:

- Meet the definition of "medical device" stated in section 201(h) of the Federal Food, Drug and Cosmetic Act
- Automatically upload patient physiologic data (i.e., data are not self-recorded and/or self-reported by the patient)
- Be capable of generating and transmitting either (a) daily recordings of the beneficiary's physiologic data, or (b) an alert if the beneficiary's values fall outside pre-determined parameters.
- 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
- Be used to collect and transmit reliable and valid physiologic data that allow understanding of a patient's health status in order to develop and manage a plan of treatment

CMS has not stated any requirements, nor offered any guidance, regarding the documentation necessary to support a claim under CPT 99453 or 99454, or the

appropriate date or place of service to be listed on the claim form. Absent such direction, we recommend the following:

- In addition to the order and consent, the documentation for CPT 99453 should include: (1) identification of the device; (2) date of delivery of the device to the patient/caregiver; and (3) date(s) on which training is provided to patient/caregiver. (The documentation for CPT 99454 should be sufficient to demonstrate monitoring occurred for at least 16 days in a 30-day period.

- The date of service for CPT 99453 is the day on which the device records the 16th day of data in a 30-day period following initiation of the service (or the last date of that 30-day period).

- If the device records and transmits data for at least 16 days, but not more than 30 days, the date of service for CPT 99454 is the last day the device records data and transmits it to the provider. If the device records and transmits data for more than 30 days, the date of service for the first instance of CPT 99454 for a given beneficiary would be 30 days following the delivery of the device or completion of training (whichever occurred later). The date of service for each instance thereafter would be 30 days from the prior date of billing, provided the use of the device continued at least 16 days after the prior date of service.

Compliance: SPAC provided a list of devices utilized for RPM, and it appears all of these devices meet the regulatory requirements. SPAC also provided examples of monitoring reports used to verify at least 16 days of data are collected monthly. We assume this data is automatically uploaded from the devices, as opposed to recording patient-reported data. We understand SPAC collects patient activity data (e.g., number of steps), but does not include that data in its count of 16 days of data for billing purposes. We have confirmed that SPAC's invoices to the practices reflect the appropriate dates of service consistent with the aforementioned billing rules.

We understand all monitoring data transmitted from the devices to SPAC's platform is immediately available to the practice through the portal. A physician in the practice may access this data to evaluate the patient's condition and determine appropriate treatment.

Conclusion

SPAC has an opportunity to enhance its relationship with the practices for which it provides care management services by developing written policies and procedures demonstrating its compliance with Medicare billing rules in the provision of those services. In the event any practice's claims for CCM, PCM, or RPM services are subject to audit or review, these written documents will demonstrate SPAC's compliance with its contractual obligations to provide care management services in a manner to permit the practice to bill and collect for those services.

Additionally, SPAC should consider a formal review of its standard agreements with practices for care management services to ensure an appropriate division of responsibilities between the parties, especially with respect to documentation of medical necessity and review of the care plan. The increase in Medicare reimbursement for CCM and PCM services in 2022 provides an opportunity for initiating these discussions with the practices.

Code	Descriptor	2021 National Payment Amount Non-Facility	2022 National Payment Amount Non-Facility	Difference
99490	CCM, clinical staff, initial 20 min.	$41.17	$64.03	+$22.86
99439	CCM, clinical staff, +20 min.	$37.69	$48.45	+$10.76
99426	PCM, clinical staff, 30 min.	$38.73	$63.34	+24.61
99427	PCM, clinical staff, +30 min.	n/a	$48.45	n/a
G0511	Care mgt., RHC/FQHC	$65.24	$79.26	+$14.02

You have inquired whether it is appropriate to bill for RPM treatment management services (CPT 99457) for those beneficiaries for whom at least 16 days of data is collected for time spent reviewing and managing these readings, in addition to CCM services. First, CPT 99457 requires direct interaction with the beneficiary in addition to time spent reviewing and managing readings. SPAC will need to ensure this interaction is provided (presumably by its care team but responsibility can be determined as part of the agreement with the provider) and appropriately documented. Second, while CMS permits billing for CPT 99457 and CPT 99490 for the same patient for the same time period, it prohibits any double-counting of time. Thus, there should be sufficient documentation to support both services independently, including a record of the time spent by clinical staff furnishing each service.