DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 417, 422, 423, 424, 425, and 460

[CMS-1654-F]

RIN 0938-AS81

Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This major final rule addresses changes to the physician fee schedule and other Medicare Part B payment policies, such as changes to the Value Modifier, to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This final rule also includes changes related to the Medicare Shared Savings Program, requirements for Medicare Advantage Provider Networks, and provides for the release of certain pricing data from Medicare Advantage bids and of data from medical loss ratio reports submitted by Medicare health and drug plans. In addition, this final rule expands the Medicare Diabetes Prevention Program model.

DATE: These regulations are effective on January 1, 2017.

FOR FURTHER INFORMATION CONTACT:

Jessica Bruton, (410) 786-5991, for issues related to identification of potentially misvalued services and any physician payment issues not identified below.

Gail Addis, (410) 786-4522, for issues related to diabetes self-management training

Jaime Hermansen, (410) 786-2064, for issues related to moderate sedation coding and anesthesia services.

Roberta Epps, (410) 786-4503, for issues related to PAMA section 218(a) policy and the transition from traditional x-ray imaging to digital radiography.

Ann Marshall, (410) 786-3059, for primary care issues related to chronic care management (CCM), burden reduction, telehealth services and evaluation and management services.

Emily Yoder, (410) 786-1804, for issues related to resource intensive services, telehealth services and other primary care issues.

Lindsey Baldwin, (410) 786-1694, for primary care issues related to behavioral health integration services.

Geri Mondowney, (410) 786–4584, and Donta Henson, (410) 786-1947, for issues related to geographic practice cost indices.

Michael Soracoe, (410) 786-6312, for issues related to the target and phase-in provisions, the practice expense methodology, impacts, conversion factor, and the valuation of pathology and surgical procedures.

Pamela West, (410) 786-2302, for issues related to therapy.

Patrick Sartini, (410) 786-9252, for issues related to malpractice RVUs, radiation treatment, mammography and other imaging services.

Kathy Bryant, (410) 786-3448, for issues related to collecting data on resources used in furnishing global services.

Donta Henson, (410) 786-1947, for issues related to ophthalmology services.

Corinne Axelrod, (410) 786-5620, for issues related to rural health clinics or federally qualified health centers.

Simone Dennis, (410) 786-8409, for issues related to FQHC-specific market basket.

JoAnna Baldwin, (410) 786-7205, or Sarah Fulton, (410) 786-2749, for issues related to appropriate use criteria for advanced diagnostic imaging services.

Robin Usi, (410) 786-0364, for issues related to open payments.

Sean O'Grady, (410) 786-2259, or Julie Uebersax, (410) 786-9284, for issues related to release of pricing data from Medicare Advantage bids and release of medical loss ratio data submitted by Medicare Advantage organizations and Part D sponsors.

Sara Vitolo, (410) 786-5714, for issues related to prohibition on billing qualified Medicare beneficiary individuals for Medicare cost-sharing.

Michelle Peterman, (410) 786-2591, for issues related to Accountable Care Organization (ACO) participants who report PQRS quality measures separately.

Katie Mucklow, (410) 786-0537 or John Spiegel, (410) 786-1909, for issues related to Provider Enrollment Medicare Advantage Program.

Jen Zhu, (410) 786-3725, Carlye Burd, (410) 786-1972, or Nina Brown, (410) 786-6103, for issues related to Medicare Diabetes Prevention Program model expansion.

Rabia Khan or Terri Postma, (410) 786-8084 or ACO@cms.hhs.gov, for issues related to the Medicare Shared Savings Program.

Kimberly Spalding Bush, (410) 786-3232, or Fiona Larbi, (410) 786-7224, for issues related to Value-based Payment Modifier and Physician Feedback Program.

Lisa Ohrin Wilson, (410) 786-8852, or Gabriel Scott, (410) 786-3928, for issues related to physician self-referral updates.

SUPPLEMENTARY INFORMATION:

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Acronyms

In addition, because of the many organizations and terms to which we refer by acronym in this final rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

A1c	Hemoglobin A1c
AAA	Abdominal aortic aneurysms
ACO	Accountable care organization
AMA	American Medical Association
ASC	Ambulatory surgical center
ATA	American Telehealth Association

permission to consult with relevant specialists including a psychiatric consultant, and inform the beneficiary that cost sharing will apply to in-person and non-face-to-face services provided. Consent may be verbal (written consent is not required) but must be documented in the medical record.

For payment purposes, we are assigning general supervision to all of the BHI service codes (G0502, G0503, G0504 and G0507). However we note that general supervision does not, by itself, comprise a qualifying relationship between the treating practitioner and other individuals providing BHI services under the incident to relationship. Also we note that we valued BHI services in both facility and non-facility settings. BHI services may be furnished to beneficiaries in any setting of care. Time that is spent furnishing BHI services to a beneficiary who is an inpatient or in any other facility setting during service provision or for any part of the service period may be counted towards reporting a BHI code(s). We refer the reader to our discussion above on this matter, as well as reporting by specialty, intersection with other services, and potential reporting by more than one practitioner for a given beneficiary within a service period. A single practitioner must choose whether to report psychiatric CoCM code(s) (G0502, G0503, and G0504 as applicable) or the general BHI code (G0507) for a given month (service period) for a given beneficiary.

4. Reducing Administrative Burden and Improving Payment Accuracy for Chronic Care Management (CCM) services

Beginning in CY 2015, we implemented separate payment for CCM services under CPT code 99490 (Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health professional, per calendar month, with the following required elements:

- Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;
- Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;
- Comprehensive care plan established, implemented, revised, or monitored).

In the CY 2015 final rule with comment period, we finalized a proposal to make separate payment for CCM services as one initiative in a series of initiatives designed to improve payment for, and encourage long-term investment in, care management services (79 FR 67715). In particular, we sought to address an issue raised to us by the physician community, which stated that the care management included in many of the existing E/M services, such as office visits, does not adequately describe the typical non-face-to-face care management work required by certain categories of beneficiaries (78 FR 43337). We began to re-examine how Medicare should pay under the PFS for non-face-to-face care management services that were bundled into the PFS payment for face-to-face E/M visits, being included in the pre- and post-encounter work (78 FR 43337). In proposing separate payment for CCM, we acknowledged that, even though we had previously considered non-face-to-face care management services as bundled into the payment for face-to-face E/M visits, the E/M office/outpatient visit CPT codes may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries. We stated that we believed that the resources required to furnish complex chronic care management services to beneficiaries with multiple (that is, two or more) chronic conditions were not adequately reflected in the existing E/M codes. Medical practice and patient complexity required physicians, other practitioners and their clinical staff to spend increasing amounts of time and effort managing the care of comorbid beneficiaries outside

of face-to-face E/M visits, for example, complex and multidisciplinary care modalities that involve regular physician development and/or revision of care plans; subsequent report of patient status; review of laboratory and other studies; communication with other health care professionals not employed in the same practice who are involved in the patient's care; integration of new information into the care plan; and/or adjustments of medical therapy.

Therefore, in the CY 2014 PFS final rule with comment period, we established a separate payment under the PFS for CPT code 99490 (78 FR 43341 through 43342). We sought to include a relatively broad eligible patient population within the code descriptor, established a moderate payment amount, and established bundled payment for concurrently new CPT codes that were reserved for beneficiaries requiring "complex" CCM services (base CPT code 99487 and its add-on code 99489) (79 FR 67716 through 67719). We stated that we would evaluate the services reported under CPT code 99490 to assess whether the service is targeted to the right population and whether the payment amount is appropriate (79 FR 67719). We remind stakeholders that CMS did not limit the eligible population to any particular list of chronic conditions other than the language in the CPT code descriptor. Accordingly, one or more of the chronic conditions being managed through CCM services could be chronic mental health or behavioral health conditions or chronic cognitive disorders, as long as the chronic conditions meet the eligibility language in the CPT code descriptor for CCM services and the billing practitioner meets all of Medicare's requirements to bill the code including comprehensive, patient-centered care planning for all health conditions.

In finalizing separate payment for CPT code 99490, we considered whether we should develop standards to ensure that physicians and other practitioners billing the service would have the capability to fully furnish the service (79 FR 67721). We sought to make certain that the

newly payable PFS code(s) would provide beneficiary access to appropriate care management services that are characteristic of advanced primary care, such as continuity of care; patient support for chronic diseases to achieve health goals; 24/7 patient access to care and health information; receipt of preventive care; patient, family and caregiver engagement; and timely coordination of care through electronic health information exchange. Accordingly, we established a set of scope of service elements and payment rules in addition to or in lieu of those established in CPT guidance (in the CPT code descriptor and CPT prefatory language), that the physician or nonphysician practitioner must satisfy to fully furnish CCM services and report CPT code 99490 (78 FR 74414 through 74427, 79 FR 67715 through 67730, and 80 FR 14854). We established requirements to furnish a preceding qualifying visit, obtain advance written beneficiary consent, use certified electronic health record (EHR) technology to furnish certain elements of the service, share the care plan and clinical summaries electronically, document specified activities, and other items summarized in Table 11 of our CY 2017 proposed rule. For the CCM service elements for which we required use of a certified EHR, the billing practitioner must use, at a minimum, technology meeting the edition(s) of certification criteria that is acceptable for purposes of the EHR Incentive Programs as of December 31st of the calendar year preceding each PFS payment year. (For the CY 2017 PFS payment year, this would mean technology meeting the 2014 edition of certification criteria).

These elements and requirements for separately payable CCM services are extensive and generally exceed those required for payment of codes describing procedures, diagnostic tests, or other E/M services under the PFS. In addition, both CPT guidance and Medicare rules specify that only a single practitioner who assumes the care management role for a given beneficiary can bill CPT code 99490 per service period (calendar month). Because the new CCM service closely

overlapped with several Medicare demonstration models of advanced primary care (the Multi-Payer Advanced Primary Care Practice (MAPCP) demonstration and the Comprehensive Primary Care Initiative (CPCI)), we provided that practitioners participating in one of these two initiatives could not be paid for CCM services furnished to a beneficiary attributed by the initiative to their practice (79 FR 67729).

Given the non-face-to-face nature of CCM services, we also sought to ensure that beneficiaries would receive advance notice that Part B cost sharing applies since we currently have no legislative authority to "waive" cost sharing for this service. Also since only one practitioner can bill for CCM each service period, we believed the beneficiary notice requirement would help prevent duplicate payment to multiple practitioners.

Since the establishment of CPT code 99490 for separate payment of CCM services, in a number of forums and in public comments to the CY 2016 PFS final rule (80 FR 70921), many practitioners have stated that the service elements and billing requirements are burdensome, redundant and prevent them from being able to provide the services to beneficiaries who could benefit from them. Stakeholders have stated that CPT code 99490 is underutilized because it is underpaid relative to the resources involved in furnishing the services, especially given the extensive Medicare rules for payment, and they have suggested a number of potential changes to our current payment rules. Stakeholders continue to believe that many of the CCM payment rules are duplicative, and to recommend that we reduce the rules and expand CCM coding and payment to distinguish among different levels of patient complexity. We also note that section 103 of the MACRA requires CMS to assess and report to Congress (no later than December 31, 2017) on access to CCM services by underserved rural and racial and ethnic minority populations and to conduct an outreach/education campaign that is underway.

The professional claims data for CPT code 99490 show that utilization is steadily increasing but may remain low considering the number of eligible Medicare beneficiaries. To date, approximately 513,000 unique Medicare beneficiaries received the service an average of four times each, totaling $93 million in total payments. Since CPT code 99490 describes a minimum of 20 minutes of clinical staff time spent furnishing CCM services during a month and does not have an upper time limit, and since we currently do not separately pay the other codes in the CCM family of CPT codes (which would provide us with utilization data on the number of patients requiring longer service times during a billing period), we do not know how often beneficiaries required more than 20 minutes of CCM services per month. We also do not know their complexity relative to one another, other than meeting the acuity criteria in the CPT code descriptor. Initial information from practitioner interviews conducted as part of our CCM evaluation efforts indicates that practitioners overwhelmingly meet and exceed the 20-minute threshold time for billing CCM. Typically, these practitioners reported spending between 45 minutes and an hour per month on CCM services for each patient, with times ranging between 20 minutes and several hours per month. CCM beneficiaries tend to exhibit a higher disease burden, are more likely to be dually eligible for Medicare and Medicaid, and are older than the general Medicare fee-for-service population.[13] However, absent multiple levels of CCM coding, we do not have comprehensive data on the relative complexity of the CCM services furnished to beneficiaries.

In light of this stakeholder feedback and our mandate under MACRA section 103 to encourage and report on access to CCM services, we proposed several changes in the payment

[13] Schurrer, John, and Rena Rudavsky. "Evaluation of the Diffusion and Impact of the Chronic Care Management (CCM) Fees: Third Quarterly Report." Report submitted to the Center for Medicare and Medicaid Innovation. Washington, DC: Mathematica Policy Research, May 6, 2016.

rules for CCM services. Our primary goal, and our statutory mandate, is to pay as accurately as possible for services furnished to Medicare beneficiaries based on the relative resources required to furnish PFS services, including CCM services. In so doing, we also expect to facilitate beneficiaries' access to reasonable and necessary CCM services that improve health outcomes. First, for CY 2017 we proposed to more appropriately recognize and pay for the other codes in the CPT family of CCM services (CPT codes 99487 and 99489 describing complex CCM), consistent with our general practice to price services according to their relative ranking within a given family of services. We direct the reader to section II.L of this final rule for a discussion of valuation for base CPT code 99487 and its add-on CPT code 99489. The CPT code descriptors are:

- CPT code 99487 – Complex chronic care management services, with the following required elements:

++ Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;

++ Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;

++ Establishment or substantial revision of a comprehensive care plan;

++ Moderate or high complexity medical decision making;

++ 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.

- CPT code 99489 – Each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure).

As CPT provides, less than 60 minutes of clinical staff time in the service period could not be reported separately, and similarly, less than 30 minutes in addition to the first 60 minutes of complex CCM in a service period could not be reported. We would require 60 minutes of services for reporting CPT code 99487 and 30 additional minutes for each unit of CPT code 99489.

We proposed to adopt the CPT provision that CPT codes 99487, 99489 and 99490 may only be reported once per service period (calendar month) and only by the single practitioner who assumes the care management role with a particular beneficiary for the service period. That is, a given beneficiary would be classified as eligible to receive either complex or non-complex CCM during a given service period , not both, and only one professional claim could be submitted to the PFS for CCM for that service period by one practitioner.

Comment: Several commenters were supportive of separate payment for complex CCM services.

Response: We thank the commenters for their support and are finalizing separate payment for CPT codes 99487 and 99489 as proposed. As finalized, these separate payments for complex CCM services will support care management for the most complex and time-consuming cases of beneficiaries with multiple chronic conditions.

Except for differences in the CPT code descriptors, we proposed to require the same CCM service elements for CPT codes 99487, 99489 and 99490. In other words, all the requirements in Table 11 of our proposed rule would apply, whether the code being billed for the service period is CPT code 99487 (plus CPT code 99489, if applicable) or CPT code 99490. These three codes would differ in the amount of clinical staff service time provided; the complexity of medical decision-making as defined in the E/M guidelines (determined by the

problems addressed by the reporting practitioner during the month); and the nature of care planning that was performed (establishment or substantial revision of the care plan for complex CCM versus establishment, implementation, revision or monitoring of the care plan for non-complex CCM). Billing practitioners could consider identifying beneficiaries who require complex CCM services using criteria suggested in CPT guidance (such as number of illnesses, number of medications or repeat admissions or emergency department visits) or the profile of typical patients in the CPT prefatory language, but these would not comprise Medicare conditions of eligibility for complex CCM.

We proposed several changes to our current scope of service elements for CCM, and proposed that the same scope of service elements, as amended, would apply to all codes used to report CCM services beginning in 2017 (i.e., CPT codes 99487, 99489 and 99490). In particular, we proposed changes in the requirements for the initiating visit, 24/7 access to care and continuity of care, format and sharing of the care plan and clinical summaries, beneficiary receipt of the care plan, beneficiary consent and documentation.

Comment: Commenters were broadly supportive of these proposals. We received several comments recommending changes to the scope of service for non-complex CCM that might improve the distinction between non-complex and complex CCM and inform which "level" of service a given beneficiary is eligible for. For example, these commenters suggested changes to the time included in the code descriptor to reflect two or more time increments for CPT code 99490 using add-on codes, or retaining the current low time threshold while allowing practitioners to choose among certain service elements. Some commenters do not believe CPT code 99490 is intended for beneficiaries who require all the current service elements in a given

month, and that only a more limited set of elements is medically necessary for the non-complex population.

Response: We appreciate the commenters' recommendations about how we might better distinguish complex CCM services from non-complex CCM services. The CPT Editorial Panel currently maintains the coding for CCM services. Further changes in codes and/or descriptors may be appropriately addressed by CPT and in subsequent PFS rulemaking.

a. CCM Initiating Visit & Add-On Code (G0506)

As provided in the CY 2014 PFS final rule with comment period (78 FR 74425) and subregulatory guidance (available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Payment_for_CCM_Services_FAQ.pdf), CCM must be initiated by the billing practitioner during a "comprehensive" E/M visit, AWV or IPPE. This face-to-face, initiating visit is not part of the CCM service and can be separately billed to the PFS, but is required before CCM services can be provided directly or under other arrangements. The billing practitioner must discuss CCM with the patient at this visit. While informed patient consent does not have to be obtained during this visit, the visit is an opportunity to obtain the required consent. The face-to-face visit included in transitional care management (TCM) services (CPT codes 99495 and 99496) qualifies as a "comprehensive" visit for CCM initiation. Levels 2 through 5 E/M visits (CPT codes 99212 through 99215) also qualify; CMS does not require the practice to initiate CCM during a level 4 or 5 E/M visit. However, CPT codes that do not involve a face-to-face visit by the billing practitioner or are not separately payable by Medicare (such as CPT code 99211, anticoagulant management, online services, telephone and other E/M services) do not qualify as initiating visits. If the practitioner furnishes a

"comprehensive" E/M, AWV, or IPPE and does not discuss CCM with the patient at that visit, that visit cannot count as the initiating visit for CCM.

We continued to believe that we should require an initiating visit in advance of furnishing CCM services, separate from the services themselves, because a face-to-face visit establishes the beneficiary's relationship with the billing practitioner and most aspects of the CCM services are furnished incident to the billing practitioner's professional services. The initiating visit also ensures collection of comprehensive health information to inform the care plan. We continued to believe that the types of face-to-face services that qualify as an initiating visit for CCM are appropriate. We did not propose to change the kinds of visits that can qualify as initiating CCM visits. However, we proposed to require the initiating visit only for new patients or patients not seen within one year instead of for all beneficiaries receiving CCM services. We believed this would allow practitioners with existing relationships with patients who have been seen relatively recently to initiate CCM services without furnishing a potentially unnecessary E/M visit. We solicited public comment on whether a period of time shorter than one year would be more appropriate.

Comment: The commenters were generally supportive of requiring the CCM initiating visit only for beneficiaries who are new patients or have not been seen in a year. A few commenters suggested a 6-month timeframe, or adopting one year and reconsidering as we gain more experience with CCM. Some commenters misinterpreted our proposal as requiring face-to-face visits every year to periodically reassess the beneficiary or the appropriateness of CCM services. Some recommended a similar coding structure for specialists managing a single condition, in place of prolonged services, or for BHI services.

Response: Our intent was to revise the timeframe for the single CCM initiating visit that is required at the outset of services. We did not propose subsequent "re-initiation" of CCM services or face-to-face reassessment within a given timeframe. We discuss further below that we have some concerns about how to ensure that the billing practitioner remains involved in the beneficiary's care and continually reassesses the beneficiary's care, but at this time we do not believe we should require subsequent face-to-face visits within certain timeframes to address those concerns.

We believe that the proposed one-year timeframe for the single, CCM initiating visit is appropriate for CY 2017, so we are finalizing as proposed. We will require the CCM initiating visit only for new patients or patients not seen within the year prior to commencement of CCM (instead of for all beneficiaries receiving CCM services). We will continue to consider in future years whether a different timeframe is warranted. The goal of our final policy is to allow practitioners with existing relationships with beneficiaries who have been seen relatively recently to initiate CCM services (for the first time) without furnishing a potentially unnecessary E/M visit. Regarding subsequent visits (after CCM services begin), practitioners are already permitted to furnish and separately bill subsequent E/M visits (or AWVs) for beneficiaries receiving CCM services. If a face-to-face reassessment is reasonable and necessary and furnished by the billing practitioner, then he or she may bill an appropriate code describing the face-to-face assessment of a beneficiary to whom they have previously furnished CCM services.

We also proposed for CY 2017 to create a new add-on G-code that would improve payment for services that qualify as initiating visits for CCM services. The code would be billable for beneficiaries who require extensive face-to-face assessment and care planning by the billing practitioner (as opposed to clinical staff), through an add-on code to the initiating visit,

G0506 (Comprehensive assessment of and care planning by the physician or other qualified health care professional for patients requiring chronic care management services (billed separately from monthly care management services) (Add-on code, list separately in addition to primary service)).

We proposed that when the billing practitioner initiating CCM personally performs extensive assessment and care planning outside of the usual effort described by the billed E/M code (or AWV or IPPE code), the practitioner could bill G0506 in addition to the E/M code for the initiating visit (or in addition to the AWV or IPPE), and in addition to the CCM CPT code 99490 (or proposed 99487 and 99489) if all requirements to bill for CCM services are also met. We proposed valuation for G0506 in a separate section of our proposed rule.

The code G0506 would account specifically for additional work of the billing practitioner in personally performing a face-to-face assessment of a beneficiary requiring CCM services, and personally performing CCM care planning (the care planning could be face-to-face and/or non-face-to-face) that is not already reflected in the initiating visit itself (nor in the monthly CCM service code). We believed G0506 might be particularly appropriate to bill when the initiating visit is a less complex visit (such as a level 2 or 3 E/M visit), although G0506 could be billed along with higher level visits if the billing practitioner's effort and time exceeded the usual effort described by the initiating visit code. It could also be appropriate to bill G0506 when the initiating visit addresses problems unrelated to CCM, and the billing practitioner does not consider the CCM-related work he or she performs in determining what level of initiating visit to bill. We believed that this proposal would more appropriately recognize the relative resource costs for the work of the billing practitioner in initiating CCM services, specifically for extensive work assessing the beneficiary and establishing the CCM care plan that is reasonable and

necessary, and that is not accounted for in the billed initiating visit or in the unit of the CCM service itself that is billed for a given service period. In addition, we believed this proposal would help ensure that the billing practitioner personally performs and meaningfully contributes to the establishment of the CCM care plan when the patient's complexity warrants it.

Comment: Several commenters were supportive of the add-on code (G0506) to the CCM initiating visit to describe physician assessment and care planning for patients requiring CCM services. Some commenters raised questions about whether G0506 should be a one-time service or could also be billed as an add-on code to subsequent reassessments by the billing practitioner (whether E/M visits or subsequent AWVs).

Response: At this time, we do not believe we should permit billing of G0506 more than once by the billing practitioner for a given beneficiary. G0506 was proposed as an add-on code to the single initiating visit, to help ensure the billing practitioner's assessment and involvement at the outset of CCM services. At this time there are no requirements for the billing practitioner to "re-initiate" CCM services; therefore we do not believe we should create an add-on code for a CCM "re-initiation" service. We would have to define "re-initiation" and develop rules regarding when subsequent E/M visits or AWVs are related to the performance of CCM. We do not believe beneficiaries would understand why they are incurring additional cost sharing for an add-on code to a "re-initiation" visit that has not been required or defined by CMS.

As we stated in the CY 2017 proposed rule, we were very interested in coding that was presented to the CPT Editorial Panel, but not adopted, to create code(s) that would separately identify and account for monthly CCM work by the billing practitioner. Such coding may be a better means of separately identifying and valuing the subsequent work of the billing practitioner after CCM is initiated. We want to establish policies that help ensure that the billing practitioner

is not merely handing the beneficiary off to a remote care manager under general supervision while no longer remaining involved in their care. We believe that the practitioner billing CCM services should be actively re-assessing the beneficiary's chronic conditions, reviewing whether treatment goals are being met, updating the care plan, performing any medical decision-making that is not within the scope of practice of clinical staff, performing any necessary face-to-face care, and performing other related work. However, it would be more straightforward to separately identify this CCM-related work under code(s) that in their own right describe it, instead of add-on codes to very broadly drawn E/M codes where it becomes difficult to assess the relationship between the two services. Also for beneficiaries receiving complex CCM, some of this work is explicitly included in the complex CCM service codes (i.e., medical decision-making of moderate to high complexity). Therefore, at this time, G0506 will only serve as an add-on code to describe work performed by the billing practitioner once, in conjunction with the start or initiation of CCM services.

We note that despite the role of the billing practitioner in the initiation and provision of CCM services provided by clinical staff, non-complex CCM (CPT code 99490) is described based on the time spent by clinical staff. Complex CCM (CPT codes 99487 and 99489) similarly counts only clinical staff time, although it also includes complex medical decision-making by the billing practitioner. This raises issues regarding appropriate valuation in the facility setting that we will continue to consider in future rulemaking. The facility PE RVU for CCM includes indirect PE (which is an allocation based on physician work), but no direct PE (which would be comprised of other labor, supplies and equipment). This is because historically, the PFS facility rate assumes that the billing practitioner is not bearing a significant resource cost in labor by other individuals, equipment or supplies. Medicare assumes that those costs are

instead borne by the facility and adequately accounted for in a separate payment made to the facility. The PFS non-facility rate generally does include such costs, assuming that the billing practitioner bears the resource costs in clinical and other staff labor, supplies and equipment.

For CCM, we have been considering whether this approach to valuation remains appropriate, because the service, in whole or in significant part, is provided by clinical staff under the direction of the billing practitioner. These individuals may provide the service or part thereof remotely, and are not necessarily employees or staff of the facility. Under this construct, there may be more direct practice expense borne by the billing practitioner that should be separately identified and valued over and above any institutional payment to the facility for its staff and infrastructure. We plan to explore these issues in future rulemaking and consider other approaches to valuation that would recognize the accurate relative resource costs to the billing practitioner for CCM and similar services furnished to beneficiaries who remain or reside in a facility setting during some or all of the service period.

Consistent with general coding guidance, we proposed that the work that is reported under G0506 (including time) could not also be reported under or counted towards the reporting of any other billed code, including any of the monthly CCM services codes. The care plan that the practitioner must create to bill G0506 would be subject to the same requirements as the care plan included in the monthly CCM services, namely, it must be an electronic patient-centered care plan based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports; a comprehensive care plan for all health issues. This would distinguish it from the more limited care planning included in the BHI codes G0502, G0503, G0504 or G0507 which focus on behavioral health issues, or the care planning included in G0505 which focuses on cognitive status. We sought public input on

potential overlap among these codes and further clinical input as to how the assessments and care planning that is included in them would differ.

We received a number of comments regarding the relationship between proposed G0506, G0505 (Cognition and functional assessment by the physician or other qualified health care professional in office or other outpatient), prolonged non-face-to-face services, and BHI. We address these comments in the sections of this final rule regarding G0505, prolonged non-face-to-face services and BHI services (sections II.E.5, II.E.2 and II.E.3). In brief, we are not allowing G0506 and G0505 to be billed the same day (by a single practitioner). G0506 will not be an add-on code for the BHI initiating visit or BHI services. G0506 will be a one-time service code for CCM initiation, and the billing practitioner must choose whether to report either G0506 or prolonged services in association with CCM initiation (if requirements to bill both are met).

The CCM and BHI service codes differ substantially in potential diagnosis and comorbidity, the expected duration of the condition(s) being treated, the kind of care planning performed (comprehensive care planning versus care planning focused on behavioral/mental health issues), service elements and who performs them, and the interventions the beneficiary needs and receives apart from the CCM and BHI services themselves. The BHI codes include a more focused process than CCM for the clinical integration of primary care and behavioral health/psychiatric care, and for continual reassessment and treatment progression to a target or goal outcome that is specific to mental and behavioral health or substance abuse issues. However there is no explicit BHI service element for managing care transitions or systematic assessment of receipt of preventive services; there is no requirement to perform comprehensive care planning for all health issues (not just behavioral health issues); and there are different emphases on medication management or medication reconciliation, if applicable. In deciding

which code(s) to report for services furnished to a beneficiary who is eligible for both CCM and BHI services, practitioners should consider which service elements were furnished during the service period, who provided them, how much time was spent, and should select the code(s) that most accurately and specifically identifies the services furnished without duplicative time counting. Practitioners should generally select the more specific code(s) when an alternative code(s) potentially includes the services provided. We are not precluding use of the CCM codes to report, or count, behavioral health care management if it is provided as part of a broader CCM service by a practitioner who is comprehensively overseeing all of the beneficiary's health issues, even if there are no imminent non-behavioral health needs. However, such behavioral care management activities could not also be counted towards reporting a BHI code(s). If a BHI service code more specifically describes the service furnished (service time and other relevant aspects of the service being equal), or if there is no focus on the health of the beneficiary outside of a narrower set of behavioral health issues, then it is more appropriate to report the BHI code(s) than the CCM code(s). Similarly, it may be more appropriate for certain specialists to bill BHI services than CCM services, since specialists are more likely to be managing the beneficiary's behavioral health needs in relation to a narrow subset of medical condition(s). CCM and BHI services can only be billed the same month for the same beneficiary if all the requirements to bill each service are separately met. We will monitor the claims data, and we welcome further stakeholder input to inform appropriate reporting rules.

b. 24/7 Access to Care, Continuity of Care, Care Plan and Managing Transitions

We proposed several revisions to the scope of service elements of 24/7 Access to Care, Continuity of Care, Care Plan and Managing Transitions. We continued to believe these elements are important aspects of CCM services, but that we should reduce the requirements for

the use of specified electronic health information technology (IT) in their provision. In sum, we proposed to retain a core requirement to use a certified electronic health record (EHR), but allow fax to count for electronic transmission of clinical summaries and the care plan; no longer require access to the electronic care plan outside of normal business hours to those providing CCM services; and remove standards for clinical summaries in managing care transitions.

We sought to improve alignment with CPT provisions by removing the requirement for the care plan to be available remotely to individuals providing CCM services after hours. Studies have shown that after-hours care is best implemented as part of a larger practice approach to access and continuity (see for example, the peer-review article available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3475839/). There is substantial local variation in how 24/7 access and continuity of care are achieved, depending on the contractual relationships among practitioners and providers in a particular geographic area and other factors. Care models include various contractual relationships between physician practices and after-hours clinics, urgent care centers and emergency departments; extended primary care office hours; physician call-sharing; telephone triage systems; and health information technology such as shared EHRs and systematic notification procedures (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3475839/). Some or all of these may be used to provide access to urgent care on a 24/7 basis while maintaining information continuity between providers.

We recognized that some models of care require more significant investment in practice infrastructure than others, for example resources in staffing or health information technology. In addition, we believed there is room to reduce the administrative complexity of our current payment rules for CCM services to accommodate a range of potential care models. In re-

examining what should be included in the CCM scope of service elements for 24/7 Access to Care and Continuity of Care, we believed the CPT language adequately and more appropriately describes the services that should, at a minimum, be included in these service elements. Therefore, we proposed to adopt the CPT language for these two elements. For 24/7 Access to Care, the scope of service element would be to provide 24/7 access to physicians or other qualified health care professionals or clinical staff including providing patients/caregivers with a means to make contact with health care professionals in the practice to address urgent needs regardless of the time of day or day of week. We believed the CPT language more accurately reflects the potential role of clinical staff or call-sharing services in addressing after-hours care needs than our current language does. In addition, the 24/7 access would be for "urgent" needs rather than "urgent chronic care needs," because we believed after-hours services typically would and should address any urgent needs and not only those explicitly related to the beneficiary's chronic conditions.

We recognized that health information systems that include remote access to the care plan or the full EHR after hours, or a feedback loop that communicates back to the primary care physician and others involved in the beneficiary's care regarding after-hours care or advice provided, are extremely helpful (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3475839/#CR25). They help ensure that the beneficiary receives necessary follow up, particularly if he or she is referred to the emergency department, and follow up after an emergency department visit is required under the CCM element of Management of Care Transitions. Accordingly, we continued to support and encourage the use of interoperable EHRs or remote access to the care plan in providing the CCM service elements of 24/7 Access to Care, Continuity of Care, and Management of Care

Transitions. However, adoption of such technology would be optimal not only for CCM services, but also for a number of other PFS services and procedures (including various other care management services), and we have not required adoption of any certified or non-certified health information technology as a condition of payment for any other PFS service. We noted that there are incentives under other Medicare programs to adopt such information technology, and were concerned that imposing too many EHR-related requirements at the service level as a condition of PFS payment could create disparities between these services and others under the fee schedule. Lastly, we recognized that not all after-hours care warrants follow-up or a feedback loop with the practitioner managing the beneficiary's care overall, and that under particular circumstances feedback loops can be achieved through oral, telephone or other less sophisticated communication methods. Therefore, we proposed to remove the requirement that the individuals providing CCM after hours must have access to the electronic care plan.

This proposal reflected our understanding that flexibility in how practices can provide the requisite 24/7 access to care, as well as continuity of care and management of care transitions, for their CCM patients could facilitate appropriate access to these services for Medicare beneficiaries. This proposal was not intended to undermine the significance of standardized communication methods as part of effective care. Instead, we recognized that other CMS initiatives (such as MIPS and APMs under the Quality Payment Program) may be better mechanisms to incentivize increased interoperability of health information systems than conditions of payment assigned to particular services under the PFS. We also anticipated that improved accuracy of payment for care management services and reduced administrative burden associated with billing for them would contribute to practitioners' capacity to invest in the best tools for managing the care of Medicare beneficiaries.

For Continuity of Care, we currently require the ability to obtain successive routine appointments "with the practitioner or a designated member of the care team," while CPT only references successive routine appointments "with a designated member of the care team." We do not believe there is any practical difference between these two phrases and therefore proposed to omit the words "practitioner or" from our requirement. The billing practitioner is a member of the CCM care team, so the CPT language already allows for successive routine appointments either with the billing practitioner or another appropriate member of the CCM care team.

Based on review of extensive public comment and stakeholder feedback, we had also come to believe that we should not require individuals providing the beneficiary with the required 24/7 access to care for urgent needs to have access to the care plan as a condition of CCM payment. As discussed above, we believed that in general, provision of effective after-hours care of the beneficiary would require access to the care plan, if not the full EHR. However, we have heard from rural and other practices that remote access to the care plan is not always necessary or possible because urgent care needs after-hours are often referred to a practitioner or care team member who established the care plan or is familiar with the beneficiary. In some instances, the care plan does not need to be available to address urgent patient needs after business hours. In addition, we have not required the use of any certified or non-certified health information technology in the provision of any other PFS services (including various other care management services). We were concerned that imposing EHR-related requirements at the service level as a condition of PFS payment could distort the relative valuation of services priced under the fee schedule. Therefore, we proposed to change the CCM service element to require timely electronic sharing of care plan information within and outside

the billing practice, but not necessarily on a 24/7 basis, and to allow transmission of the care plan by fax.

We acknowledged that it is best for practitioners and providers to have access to care plan information any time they are providing services to beneficiaries who require CCM services. This proposal was not intended to undermine the significance of electronic communication methods other than fax transmission in providing effective, continuous care. On the contrary, we believed that fax transmission, while commonly used, is much less efficient and secure than other methods of communicating patient health information, and we encouraged practitioners to adopt and use electronic technologies other than fax for transmission and exchange of the CCM care plan. We continued to believe the best means of exchange of all relevant patient health information is through standardized electronic means. However, we recognized that other CMS initiatives (such as MIPS and APMs under the Quality Payment Program) may be better mechanisms to incentivize increased interoperability of health information systems than conditions of payment assigned to particular services under the PFS. We believed our proposal would still allow timely availability of health information within and outside the practice for purposes of providing CCM, and would simplify the rules governing provision of the service and improve access to the service. The proposed revisions would better align the service with appropriate CPT prefatory language, which may reduce unnecessary administrative complexity for practitioners in navigating the differences between CPT guidance and Medicare rules.

The CCM scope of service element Management of Care Transitions includes a requirement for the creation and electronic transmission and exchange of continuity of care documents referred to as “clinical summaries” (see Table 11 of the CY 2017 PFS proposed rule).

We patterned our requirements regarding clinical summaries after the EHR Incentive Program requirement that an eligible professional who transitions their patient to another setting of care or provider of care, or refers their patient to another provider of care, should provide a summary care record for each transition of care or referral. This clinical summary includes demographics, the medication list, medication allergy list, problem list, and a number of other data elements if the practitioner knows them. As a condition of CCM payment, we required standardized content for clinical summaries (that they must be created/formatted according to certified EHR technology). For the exchange/transport function, we did not require the use of a specific tool or service to exchange/transmit clinical summaries, as long as they are transmitted electronically (this can include fax only when the receiving practitioner or provider can only receive by fax).

Based on review of extensive public comment and stakeholder feedback, we had come to believe that we should not require the use of any specific electronic technology in managing a beneficiary's care transitions as a condition of payment for CCM services. Instead, we proposed more simply to require the billing practitioner to create and exchange/transmit continuity of care document(s) timely with other practitioners and providers. To avoid confusion with the requirements of the EHR Incentive Programs, and since we would no longer require standardized content for the CCM continuity of care document(s), we would refer to them as continuity of care documents instead of clinical summaries. We would no longer specify how the billing practitioner must transport or exchange these document(s), as long as it is done timely and consistent with the Care Transitions Management scope of service element. We welcomed public input on how we should refer to these document(s), noting that CPT does not provide model language specific to CCM services. The proposed term "continuity of care document(s)" draws on CPT prefatory language for TCM services, which CPT provides may include

"obtaining and reviewing the discharge information (for example, discharge summary, as available, or continuity of care document)."

Again, this proposal was not intended to undermine the significance of a standardized, electronic format and means of exchange (other than fax) of all relevant patient health information, for achieving timely, seamless care across settings especially after discharge from a facility. On the contrary, we believed that fax transmission, while commonly used, is much less efficient and secure than other methods of communicating patient health information, and we encourage practitioners to adopt and use electronic technologies other than fax for transmission and exchange of continuity of care documents in providing CCM services. We continued to believe the best means of exchange of all relevant patient health information is through standardized electronic means. However, as we discussed above regarding the CCM care plan, we have not applied similar requirements to other PFS services specifically (including various other care management services) and had concerns about how doing so may create disparities between these services and others under the PFS. We also recognized that other CMS initiatives (such as MIPS and APMs under the Quality Payment Program) may be better mechanisms to incentivize increased interoperability of health information systems than conditions of payment assigned to particular services under the PFS.

Comment: Most of the commenters supported our proposed revisions to the health IT use requirements for billing the CCM code. They shared CMS' goal of interoperability but believed the changes were necessary to improve CCM uptake. Some commenters favored hardship exceptions or rural or small practice exceptions instead of changes to the current requirements that would apply to all practitioners alike. Some commenters expressed particular concern about relaxing the current rules in instances where CCM outsourcing reduces clinical integration.

These commenters noted that CCM is commonly outsourced to third party companies that provide remote care management services (including after hours) via telephone and online contact only, using staff who have no established relationship with the beneficiary or other members of the care team and have no interaction with the office staff and physicians other than electronic communication. These commenters were concerned that our proposed changes to the health IT requirements for CCM payment would result in little to no oversight or guidance of the third party, and recommended that CMS make the proposed changes cautiously. One of these commenters recommended in addition that CMS should seek to increase access to CCM services and reduce administrative burden by pursuing alignment between the provision of CCM and other programs and incentives, such as the Quality Payment Program. Other commenters recommended further reduction in payment rules, such as removing all requirements to use a certified EHR, or movement away from timed codes that require documentation in short time increments and disrupt workflow.

Response: We continue to believe that other Medicare initiatives and programs (such as MIPS and APMs under the Quality Payment Program) are better suited to advance use of interoperable health IT systems than establishing code-level conditions of payment, unique to CCM or other primary care or cognitive services. We also believe that a hardship, rural or small practice exception would greatly increase rather than decrease administrative complexity for practitioners and CMS, and CCM uptake has been relatively high among solo practices. We believe that reducing code-level conditions of payment is necessary to improve beneficiary access to appropriate CCM services. Therefore, we are finalizing revisions to the CCM scope of service elements as proposed.

However, we appreciate the commenters' feedback that relaxing the health IT use requirements may be of particular concern in situations where CCM is outsourced to a third party, reducing clinical integration. As we discuss in the section of this final rule on BHI services (section II.E.3.b), health IT holds significant promise for remote connectivity and interoperability that may assist and be useful (if not necessary) for reducing care fragmentation. However, we agree that remote provision of services by entities having only a loose association with the treating practitioner can detract from continuous, patient-centered care, whether or not those entities employ certified or other electronic technology. We will continue to consider the potential impacts of remote provision of CCM and similar types of services by third parties. We wish to emphasize for CCM, as we did for BHI services, that while the CCM codes do not explicitly count time spent by the billing practitioner, they are valued to include work performed by the billing practitioner, especially complex CCM. We emphasize that the practitioner billing for CCM must remain involved in ongoing oversight, management, collaboration and reassessment as appropriate to bill CCM services. If there is little oversight by the billing practitioner or a lack of clinical integration between a third party providing CCM and the billing practitioner, we do not believe that the CCM service elements are actually being furnished and therefore, in such cases, the practitioner should not bill for CCM.

Finally, we note that activities undertaken as part of participation in MIPS or an APM under the Quality Payment Program may support the ability of a practitioner to meet our final requirements for the continuity of care document(s) and the electronic care plan.

Comment: Several commenters recommended that we define the proposed term "timely" for the creation and transmission of care plan and care transitions health information. Several

commenters believed that "timely" implies a time period of 30 to 90 days, or believed some third party vendors would interpret the term in this manner.

Response: Our proposal of the term "timely" originated from the use of this term in the CPT prefatory language for Care Management services, which includes, for example, "provide timely access and management for follow-up after an emergency department visit" and "timely access to clinical information." We do not believe we should specify a timeframe, because it would vary for individual patients and CCM service elements, we are not aware of any clinical standards referencing specific times, and we are seeking to allow appropriate flexibility in how CCM is furnished. We note that dictionary meanings of the term "timely" include quickly; soon; promptly; occurring at a suitable time; done or occurring at a favorable or useful time; opportune. "Timely" does not necessarily imply speed, and means doing something at the most appropriate moment. Therefore we believe "timely" is an appropriate term to use to govern how quickly the health information in question is transmitted or available. We note that even the current requirements for use of specific electronic technology do not necessarily impact how quickly the health information in question is used to inform care, and addition of the word "timely" implies more regarding actual use of the information. We are monitoring CCM uptake and diffusion through claims analysis and are pursuing claims-based outcomes analyses, to help inform whether the service is being provided as intended and improving health outcomes. We believe these evaluation activities will help us assess moving forward whether health information is being shared or made available timely enough under our revised CCM payment policies.

As we stated in the CY 2017 proposed rule, the policy changes for CCM health IT use are not intended to undermine the importance of interoperability or electronic data exchange. These changes are driven by concerns that we have not applied similar requirements to other PFS

services specifically, including various other care management services, and that such requirements create disparities between CCM services and other PFS services. We believe that other CMS initiatives may be better mechanisms to incentivize increased use and interoperability of health information systems than conditions of payment assigned to particular services under the PFS. We anticipate that these CCM policy changes will improve practitioners' capacity to invest in the best tools for managing the care of Medicare beneficiaries.

c. Beneficiary Receipt of Care Plan

We proposed to simplify the current requirement to provide the beneficiary with a written or electronic copy of the care plan, by instead adopting the CPT language specifying more simply that a copy of the care plan must be given to the patient or caregiver. While we believe beneficiaries should and must be provided a copy of the care plan, and that practitioners may choose to provide the care plan in hard copy or electronic form in accordance with patient preferences, we do not believe it is necessary to specify the format of the care plan that must be provided as a condition of CCM payment. Additionally, we recognize that there may be times that sharing the care plan with the caregiver (in a manner consistent with applicable privacy and security rules and regulations) may be appropriate.

Comment: The commenters who provided comments on this particular proposal were supportive of it. In particular, several commenters expressed appreciation for appropriate inclusion of caregivers.

Response: We thank the commenters for their support and are finalizing as proposed.

d. Beneficiary Consent

We continue to believe that obtaining advance beneficiary consent to receive CCM services is important to ensure the beneficiary is informed, educated about CCM services, and is

aware of applicable cost sharing. We also believe that querying the beneficiary about whether another practitioner is already providing CCM services helps to reduce the potential for duplicate provision or billing of the services. However, we believe the consent process could be simplified, and that it should be left to the practitioner and the beneficiary to decide the best way to establish consent. Therefore, we proposed to continue to require billing practitioners to inform the beneficiary of the currently required information (that is, inform the beneficiary of the availability of CCM services; inform the beneficiary that only one practitioner can furnish and be paid for these services during a calendar month; and inform the beneficiary of the right to stop the CCM services at any time (effective at the end of the calendar month)). However, we proposed to specify that the practitioner could document in the beneficiary's medical record that this information was explained and note whether the beneficiary accepted or declined CCM services instead of obtaining a written agreement.

We also proposed to remove the language requiring beneficiary authorization for the electronic communication of his or her medical information with other treating providers as a condition of payment for CCM services, because under federal regulations that implement the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR 164.506), a covered entity is permitted to use or disclose protected health information for purposes of treatment without patient authorization. Moreover, if such disclosure is electronic, the HIPAA Security Rule requires secure transmission (45 CFR 164.312(e)). In previous regulations we have reminded practitioners that for all electronic sharing of beneficiary information in the provision of CCM services, HIPAA Privacy and Security Rule standards apply in the usual manner (79 FR 67728).

Comment: The commenters were largely supportive of our proposed policy changes. The commenters were supportive of verbal instead of written beneficiary consent if a clear requirement remains to transparently inform the beneficiary about the nature and benefit of the services, applicable cost sharing, and document that this information was conveyed; current written agreements qualify; and practitioners can elect to obtain written consent. Some commenters believed that obtaining written consent might be preferable as a means of resolving who is eligible for payment, if more than one practitioner bills. A few commenters suggested CMS require written educational materials about CCM, or conduct beneficiary outreach and education.

Response: We appreciate the commenters' support and recommendations. We are finalizing changes to the beneficiary consent requirements as proposed and clarifying that a clear requirement remains to transparently inform the beneficiary about the nature and benefit of the services, applicable cost sharing, and to document that this information was conveyed. The final beneficiary consent requirements do not affect any written agreements that are already in place for CCM services, and we note that practitioners can still elect to obtain written consent rather than verbal consent.

e. Documentation

We have heard from practitioners that the requirements to document certain information in a certified EHR format are redundant because the CCM billing rules already require documentation of core clinical information in a certified EHR format. Specifically, we already require structured recording of demographics, problems, medications and medication allergies, and the creation of a clinical summary record, using a qualifying certified EHR; and that a full list of problems, medications and medication allergies in the EHR must inform the care plan,

care coordination and ongoing clinical care. Therefore, we proposed to no longer specify the use of a qualifying certified EHR to document communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits and to document beneficiary consent. We would continue to require documentation in the medical record of beneficiary consent (discussed above) and of communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits.

Comment: Many commenters were supportive of these proposals.

Response: We thank the commenters for their support and are finalizing changes to the documentation requirements as proposed. We continue to encourage practitioners to utilize health IT solutions for obtaining and documenting health information from sources external to their practice, noting that the 2015 edition of ONC certification criteria (see 80 FR 62601) includes criteria which specifically relate to obtaining information from non-clinical sources and the capture of structured data relating to social, psychological, and behavioral attributes.

f. Summary of Final CCM Policies

We are finalizing changes to the CCM scope of service elements discussed above that will apply for both complex and non-complex CCM services beginning in CY 2017. The final CY 2017 service elements for CCM are summarized in Table 11. We believe these changes will retain elements of the CCM service that are characteristic of the changes in medical practice toward advanced primary care, while eliminating redundancy, simplifying provision of the services, and improving access to the services. For payment of complex CCM services beginning in CY 2017, we are adopting the CPT code descriptors for CPT codes 99487 and 99489 as well as the service elements in Table 11. We are providing separate payment for complex CCM (CPT 99487, 99489) using the RUC-recommended payment inputs for those

services. We may reconsider the role of health information technology in CCM service provision in future years. We anticipate that improved accuracy of payment for CCM services, and reduced administrative burden associated with billing CCM services, will contribute to practitioners' capacity to invest in the best tools for managing the care of Medicare beneficiaries.

TABLE 11: Summary of CY 2017 Chronic Care Management Service Elements and Billing Requirements

Initiating Visit- Initiation during an AWV, IPPE, or face-to-face E/M visit (Level 4 or 5 visit not required), for new patients or patients not seen within 1 year prior to the commencement of chronic care management (CCM) services.
Structured Recording of Patient Information Using Certified EHR Technology – Structured recording of demographics, problems, medications and medication allergies using certified EHR technology. A full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care.
24/7 Access & Continuity of Care • Provide 24/7 access to physicians or other qualified health care professionals or clinical staff including providing patients/caregivers with a means to make contact with health care professionals in the practice to address urgent needs regardless of the time of day or day of week. • Continuity of care with a designated member of the care team with whom the beneficiary is able to schedule successive routine appointments.
Comprehensive Care Management- Care management for chronic conditions including systematic assessment of the beneficiary's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of beneficiary self-management of medications.
Comprehensive Care Plan • Creation, revision and/or monitoring (as per code descriptors) of an electronic patient-centered care plan based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports; a comprehensive care plan for all health issues. • Must at least electronically capture care plan information, and make this information available timely within and outside the billing practice as appropriate. Share care plan information electronically (can include fax) and timely within and outside the billing practice to individuals involved in the beneficiary's care. • A copy of the plan of care must be given to the patient and/or caregiver.
Management of Care Transitions • Management of care transitions between and among health care providers and settings, including referrals to other clinicians; follow-up after an emergency department visit; and follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities. • Create and exchange/transmit continuity of care document(s) timely with other practitioners and providers.
Home- and Community-Based Care Coordination • Coordination with home and community based clinical service providers. • Communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits must be documented in the patient's medical record.
Enhanced Communication Opportunities- Enhanced opportunities for the beneficiary and any caregiver to communicate with the practitioner regarding the beneficiary's care through not only telephone access, but also through the use of secure messaging, Internet, or other asynchronous non-face-to-face consultation methods.
Beneficiary Consent • Inform the beneficiary of the availability of CCM services; that only one practitioner can furnish and be paid for these services during a calendar month; and of their right to stop the CCM services at any time (effective at the end of the calendar month). • Document in the beneficiary's medical record that the required information was explained and whether the beneficiary accepted or declined the services.
Medical Decision-Making- Complex CCM services require and include medical decision-making of moderate to high complexity (by the physician or other billing practitioner).

Comment: Multiple commenters suggested additional coding changes to improve payment accuracy for services for people with disabilities. Several commenters requested that CMS broaden the scope of G0501 and the codes with which it may be billed, for example by allowing G0501 to be billed with preventive services, such as the Initial Preventive Physical Examination (IPPE) or "Welcome to Medicare Visit", the Annual Wellness Visit, or other preventive services including those that have been assigned a grade of A or B by the United States Preventive Services Task Force. One commenter suggested that CMS also establish payment for a lower-level, lower payment add-on code for use with patients with a mobility-related disability that may not require the use of specialized equipment. Commenters also suggested that CMS establish certain forms of physician payment incentives, which might more effectively address the accessibility needs of individuals with disabilities and ultimately reduce healthcare disparities. Specifically, one commenter suggested CMS incentivize physicians to establish record-keeping to inquire into patients' accessibility and accommodation needs, record the needs of their patients, and take action to meet those needs over time.

Response: We thank commenters for their thoughtful responses. We reiterate our commitment to addressing disparities for individuals with disabilities and advancing health equity, and will continue to explore and revisit potential solutions for overcoming these significant challenges, including the appropriate changes in payment.

7. Regulation Text

Our current regulations in 42 CFR 410.26(b) provide for an exception to assign general supervision to CCM services (and similarly, for the non-face-to-face portion of TCM services), because these are generally non-face-to-face care management/care coordination services that would commonly be provided by clinical staff when the billing practitioner (who is also the

supervising practitioner) is not physically present; and the CPT codes are comprised solely (or in significant part) of non-face-to-face services provided by clinical staff. A number of codes that we proposed to establish for separate payment in CY 2017 under our initiative to improve payment accuracy for primary care and care management are similar to CCM services, in that a critical element of the services is non-face-to-face care management/care coordination services provided by clinical staff or other qualified individuals when the billing practitioner may not be physically present. Accordingly, we proposed to amend 42 CFR 410.26(a)(3) and 410.26(b) to better define general supervision and to assign general supervision not only to CCM services and the non-face-to-face portion of TCM services, but also to proposed codes G0502, G0503, G0504, G0507, CPT code 99487, and CPT code 99489. Instead of adding each of these proposed codes assigned general supervision to the regulation text on an individual basis, we proposed to revise our regulation under 42 CFR 410.26(b)(1) to assign general supervision to the non-face-to-face portion of designated care management services, and we would designate the applicable services through notice and comment rulemaking.

We did not receive any public comments on our proposed regulation text. However we received a number of comments regarding a related proposal to require behavioral health care managers to be located on site. Also for psychiatric CoCM services (G0502, G0503 and G0504), we are finalizing a requirement that the behavioral health care manager is available to perform his or her duties face-to-face and non-face-to-face with the beneficiary. We address these issues at length in the BHI section of this final rule (section II.E.3). Since we are assigning general supervision to psychiatric CoCM behavioral health care manager services that may be provided face-to-face with the beneficiary, we are omitting the phrase "non-face-to-face portion of" in "the non-face-to-face portion of designated care management services." Accordingly, the final

amended regulation text in 42 CFR 410.26(b) assigns general supervision to "designated care management services" that we will designate through notice and comment rulemaking. The services that we are newly designating (finalizing) for general supervision in this final rule are G0502, G0503, G0504, G0507, CPT code 99487 and CPT code 99489. We had initially proposed adding a cross-reference to the existing definition of "general supervision" in current regulations at §410.32(b)(3)(i), but to better describe general supervision in the context of these services, we are specifying at §410.26(a)(3) that general supervision means the service is furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service. At §410.26(b)(5), we specify that, in general, services and supplies must be furnished under the direct supervision of the physician (or other practitioner). Designated care management services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided incident to the services of a physician (or other practitioner). The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) who is treating the patient more broadly. However, only the supervising physician (or other practitioner) may bill Medicare for incident to services.

8. CCM Requirements for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).

RHCs and FQHCs have been authorized to bill for CCM services since January 1, 2016, and are paid based on the Medicare PFS national average non-facility payment rate when CPT code 99490 is billed alone or with other payable services on a RHC or FQHC claim. The RHC and FQHC requirements for billing CCM services have generally followed the requirements for

practitioners billing under the PFS, with some adaptations based on the RHC and FQHC payment methodologies.

To assure that CCM requirements for RHCs and FQHCs are not more burdensome than those for practitioners billing under the PFS, we proposed revisions for CCM services furnished by RHCs and FQHCs similar to the revisions proposed under the section above entitled, "Reducing Administrative Burden and Improving Payment Accuracy for Chronic Care Management (CCM) Services" for RHCs and FQHCs. Specifically, we proposed to:

- Require that CCM be initiated during an AWV, IPPE, or comprehensive E/M visit only for new patients or patients not seen within one year. This would replace the requirement that CCM could only be initiated during an AWV, IPPE, or comprehensive E/M visit where CCM services were discussed.

- Require 24/7 access to a RHC or FQHC practitioner or auxiliary personnel with a means to make contact with a RHC or FQHC practitioner to address urgent health care needs regardless of the time of day or day of week. This would replace the requirement that CCM services be available 24/7 with health care practitioners in the RHC or FQHC who have access to the patient's electronic care plan to address his or her urgent chronic care needs, regardless of the time of day or day of the week.

- Require timely electronic sharing of care plan information within and outside the RHC or FQHC, but not necessarily on a 24/7 basis, and expands the circumstances under which transmission of the care plan by fax is allowed. This would replace the requirement that the electronic care plan be available on a 24/7 basis to all practitioners within the RHC or FQHC whose time counts towards the time requirement for the practice to bill the CCM code, and

removes the restriction on allowing the care plan to be faxed only when the receiving practitioner or provider can only receive clinical summaries by fax.

- Require that in managing care transitions, the RHC or FQHC creates, exchanges, and transmits continuity of care document(s) in a timely manner with other practitioners and providers. This would replace the requirements that clinical summaries must be created and formatted according to certified EHR technology, and the requirement for electronic exchange of clinical summaries by a means other than fax.

- Require that a copy of the care plan be given to the patient or caregiver. This would remove the description of the format (written or electronic) and allows the care plan to be provided to the caregiver when appropriate (and in a manner consistent with applicable privacy and security rules and regulations).

- Require that the RHC or FQHC practitioner documents in the beneficiary's medical record that all the elements of beneficiary consent (for example, that the beneficiary was informed of the availability of CCM services; only one practitioner can furnish and be paid for these services during a calendar month; the beneficiary may stop the CCM services at any time, effective at the end of the calendar month, etc.) were provided, and whether the beneficiary accepted or declined CCM services. This would replace the requirement that RHCs and FQHCs obtain a written agreement that these elements were discussed, and removes the requirement that the beneficiary provide authorization for the electronic communication of his or her medical information with other treating providers as a condition of payment for CCM services.

- Require that communication to and from home- and community-based providers regarding the patient's psychosocial needs and functional deficits be documented in the patient's

medical record. This would replace the requirement to document this patient health information in a certified EHR format.

We noted that we did not propose an additional payment adjustment for patients who require extensive assessment and care planning as part of the initiating visit, as payments for RHC and FQHC services are not adjusted for length or complexity of the visit.

We stated that we believe these proposed changes would keep the CCM requirements for RHCs and FQHCs consistent with the CCM requirements for practitioners billing under the PFS, simplify the provision of CCM services by RHCs and FQHCs, and improve access to these services without compromising quality of care, beneficiary privacy, or advance notice and consent.

We received 31 comments on the proposed revisions to the CCM requirements for RHCs and FQHCs. The following is a summary of the comments we received:

Comment: Commenters stated that they support CMS's efforts to ensure that CCM requirements for RHCs and FQHCs are not more burdensome than those for practitioners billing under the Medicare PFS.

Response: We appreciate the support of the commenters.

Comment: One commenter sought clarification on the requirements for initiating CCM with patients that have been seen in the RHC within the past year. The commenter asked if CCM could be initiated if the patient had any type of visit within the past year, or if the visit within the past year had to be an AWV, IPPE, or comprehensive E/M visit.

Response: To initiate CCM with a patient that has been seen in the RHC or FQHC within the past year, an AWV, IPPE, or comprehensive E/M visit must have taken place within the past

year in the RHC or FQHC that is billing for the CCM service. No other type of visit would meet the requirement for initiating CCM services.

Comment: A few commenters were concerned that RHCs and FQHCs were charging beneficiaries for coinsurance for non-face-to-face services, and recommended that the copayment be waived or that CMS pursue waivers of cost-sharing for care coordination codes. One of these commenters stated that patients are often unwilling to pay the patient share of the CCM services since rural providers often have already been providing similar services without additional cost to the patients.

Response: As previously stated, we do not have the authority to waive the copayment requirements for CCM services. While many practitioners, including those in rural areas, have always provided some care management services, we believe that payment for CCM services will enable many RHCs and FQHCs to furnish comprehensive and systematic care coordination services that were previously unavailable or only sporadically offered.

Comment: A commenter asked for clarification on how claims for patients in RHCs and FQHCs with pre-existing care management plans should be handled, and suggested that CMS permit claims for services for these patients.

Response: We are not entirely clear what this commenter is suggesting. RHCs and FQHCs that bill for CCM services must develop a comprehensive care plan that includes all the elements previously described and also listed in Table 11. When all the requirements for furnishing CCM services are met, including the development of the comprehensive care plan, the RHC or FQHC would submit a claim for CCM payment using CPT code 99490. Only the time spent furnishing CCM services after CCM is initiated with the patient is counted toward the minimum 20 minutes required for CCM billing. There is no additional payment for a pre-

existing care plan, and if a comprehensive care plan that meets the CCM requirements was developed before the initiation of CCM services, the time spent developing the plan would not be counted toward the 20 minute minimum requirement.

Comment: A few commenters requested clarification on whether RHCs and FQHCs could bill the new CCM codes for either complex CCM services (CPT 99487 and 99489) or the separately billable comprehensive CCM assessment and care planning (G0506).

Response: As we noted in the proposed rule, we did not propose to adopt codes to provide for an additional payment for patients who require extensive assessment or care planning because payments for RHC and FQHC services are not adjusted for the length or complexity of the visit. Therefore, the codes identified by the commenters are not separately billable by an RHC or FQHC.

Comment: A few commenters recommended that CMS allow RHCs and FQHCs to bill for the new CCM codes, and to allow safety net providers to bill for preventive services in addition to the all-inclusive rate for RHCs and the PPS rate for FQHCs. The commenters stated that the payment structure for RHCs and FQHCs are a disincentive to provide preventative services in addition to E/M services at the same visit.

Response: RHCs and FQHCs are paid for CCM services when CPT code 99490 is billed either alone or with other payable services on a RHC or FQHC claim. The RHC and FQHC payment structures and payment for preventive services is outside the scope of this final rule.

Comment: Several commenters recommended that CMS provide separate payment for psychiatric collaborative care management services furnished in RHCs and FQHCs, including CPT codes G0502, G0503, G0504 and G0507. The commenters stated that allowing RHCs and FQHCs to bill for these services will ensure that their patients who have been diagnosed with a

mental health or substance use disorder have access to high-quality care tailored to their individual condition and circumstances.

Response: To be eligible for CCM services, a Medicare beneficiary must have two or more chronic conditions that are expected to last at least 12 months (or until the death of the patient), and place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. While CCM is typically associated with primary care conditions, patient eligibility is determined by the RHC or FQHC practitioner, and mental health conditions are not excluded. We invite comments on whether an additional code specifically for mental health conditions is necessary for RHCs and FQHCs that want to include beneficiaries with mental health conditions in their CCM services.

After considering the comments, we are finalizing as proposed the revisions to the requirements for CCM services furnished by RHCs and FQHCs.

III. Other Provisions of the Final Rule for PFS

A. Chronic Care Management (CCM) and Transitional Care Management (TCM) Supervision Requirements in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In the CY 2016 PFS final rule with comment period (80 FR 71080 through 71088), we finalized policies for payment of CCM services in RHCs and FQHCs. Payment for CCM services in RHCs and FQHCs was effective beginning on January 1, 2016, for RHCs and FQHCs that furnish a minimum of 20 minutes of qualifying CCM services during a calendar month to patients with multiple (two or more) chronic conditions that are expected to last at least 12 months or until the death of the patient, and that would place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. Payment is made when CPT code 99490 is billed alone or with other payable services on a RHC or FQHC claim, and the rate is based on the PFS national average non-facility payment rate. The requirement that RHC or FQHC services be furnished face-to-face was waived for CCM services furnished to a RHC or FQHC patient because CCM services are not required to be furnished face-to-face.

Medicare payment for TCM services furnished by a RHC or FQHC practitioner was effective January 1, 2013, consistent with the effective date of payment for TCM services under the PFS (77 FR 68978 through 68994; also, see CMS-Pub. 100-02, Medicare Benefit Policy Manual, chapter 13, section 110.4).

TCM services are billable only when furnished within 30 days of the date of the patient's discharge from a hospital (including outpatient observation or partial hospitalization), skilled nursing facility, or community mental health center. Communication (direct contact, telephone, or electronic) with the patient or caregiver must commence within 2 business days of discharge, and a face-to-face visit must occur within 14 days of discharge for moderate complexity decision

making (CPT code 99495), or within 7 days of discharge for high complexity decision making (CPT code 99496). The TCM visit is billed on the day that the TCM visit takes place, and only one TCM visit may be paid per beneficiary for services furnished during that 30 day post-discharge period. If the TCM visit occurs on the same day as another billable visit, only one visit may be billed. TCM and CCM cannot be billed during the same time period for the same patient.

In the CY 2016 PFS final rule with comment period (80 FR 71087), we responded to comments requesting that we make an exception to the supervision requirements for auxiliary personnel furnishing CCM and TCM services incident to physician services in RHCs and FQHCs (80 FR 71087). Auxiliary personnel in RHCs and FQHCs furnish services incident to a RHC or FQHC visit and include nurses, medical assistants, and other clinical personnel who work under the direct supervision of a RHC or FQHC practitioner. The commenters suggested that the regulatory language be amended to be consistent with the provision in §410.26(b)(5) for CCM and TCM services under the PFS, which states that services and supplies furnished incident to CCM and TCM services can be furnished under general supervision of the physician (or other practitioner) when they are provided by clinical staff. It further specifies that the physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based, but only the supervising physician (or other practitioner) may bill Medicare for incident to services. We responded that due to the differences between physician offices and RHCs and FQHCs in their models of care and payment structures, we believe that the direct supervision requirement for services furnished by auxiliary personnel is appropriate for RHCs and FQHCs,

but that we would consider changing this in future rulemaking if RHCs and FQHCs found that requiring direct supervision presents a barrier to furnishing CCM services.

Since payment for CCM in RHCs and FQHCs began on January 1, 2016, some RHCs and FQHCs have informed us that, in their view, the direct supervision requirement for auxiliary personnel has limited their ability to furnish CCM services. Specifically, these RHCs and FQHCs have stated that the direct supervision requirement prevented them from entering into contracts with third party companies to provide CCM services, especially during hours that they were not open, and that they were unable to meet the CCM requirements within their current staffing and budget constraints.

To bill for CCM services, RHCs and FQHCs must ensure that there is access to care management services on a 24 hour a day, 7 day a week basis. This includes providing the patient with a means to make timely contact with RHC or FQHC practitioners who have access to the patient's electronic care plan to address his or her urgent chronic care needs. The RHC or FQHC must ensure the care plan is available electronically at all times to anyone within the RHC or FQHC who is providing CCM services.

Once the RHC or FQHC practitioner has initiated CCM services and the patient has consented to receiving this service, CCM services can be furnished by a RHC or FQHC practitioner, or by auxiliary personnel, as defined in §410.26(a)(1), which includes nurses, medical assistants, and other personnel working under physician supervision who meet the requirements to provide incident to services. Auxiliary personnel in RHCs and FQHCs must furnish services under direct supervision, which requires that a RHC or FQHC practitioner be present in the RHC or FQHC and immediately available to furnish assistance and direction. The

RHC or FQHC practitioner does not need to be present in the room when the service is furnished.

Although many RHCs and FQHCs prefer to furnish CCM and TCM services utilizing existing personnel, some RHCs and FQHCs would like to contract with a third party to furnish aspects of their CCM and TCM services, but cannot do so because of the direct supervision requirement. Without the ability to contract with a third party, these RHCs and FQHCs have stated that they find it difficult to meet the CCM requirements for 24 hours a day, 7 days a week access to services.

To enable RHCs and FQHCs to effectively contract with third parties to furnish aspects of CCM and TCM services, we proposed to revise §405.2413(a)(5) and §405.2415(a)(5) to state that services and supplies furnished incident to CCM and TCM services can be furnished under general supervision of a RHC or FQHC practitioner. The proposed exception to the direct supervision requirement would apply only to auxiliary personnel furnishing CCM or TCM incident to services, and would not apply to any other RHC or FQHC services. The proposed revisions for CCM and TCM services and supplies furnished by RHCs and FQHCs are consistent with §410.26(b)(5), which allows CCM and TCM services and supplies to be furnished by clinical staff under general supervision when billed under the PFS.

The following is a summary of the comments we received on revising the supervision requirements for RHCs and FQHCs to allow general supervision for auxiliary personnel furnishing CCM or TCM services.

Comment: We received 23 comments on our proposal to allow services and supplies furnished incident to CCM and TCM services to be furnished under general supervision of a RHC or FQHC practitioner. All commenters supported this change.

Response: We appreciate the support for this proposal.

Comment: One commenter urged CMS to use the Advisory Panel on Hospital Outpatient Payment to determine RHC and FQHC supervision levels.

Response: Auxiliary personnel in RHCs and FQHCs work under direct supervision of a RHC or FQHC practitioner (consistent with statutory and regulatory authority), and we proposed to make an exception for CCM and TCM services because they are the only RHC and FQHC services that have a non-face-to-face component. We do not foresee any additional exceptions to this policy.

After considering the comments, we are finalizing this policy to revise §405.2413(a)(5) and §405.2415(a)(5) to state that services and supplies furnished incident to CCM and TCM services can be furnished under general supervision of a RHC or FQHC practitioner.