

E. Improving Payment Accuracy for Primary Care, Care Management and Patient-Centered Services

1. Overview

In recent years, we have undertaken ongoing efforts to support primary care and patient-centered care management within the PFS as part of HHS' broader efforts to achieve better care, smarter spending and healthier people through delivery system reform. We have recognized the need to improve payment accuracy for these services over several years, especially beginning in the CY 2012 PFS proposed rule (76 FR 42793) and continuing in each subsequent year of rulemaking. In the CY 2012 proposed rule, we acknowledged the limitations of the current code set that describes evaluation and management (E/M) services within the PFS. For example, E/M services represent a high proportion of PFS expenditures, but have not been recently revalued to account for significant changes in the disease burden of the Medicare patient population and changes in health care practice that are underway to meet the current population's health care needs. These trends in the Medicare population and health care practice have been widely recognized in the provider community and by health services researchers and policymakers alike.¹ We believe the focus of the health care system has shifted to delivery system reforms, such as patient-centered medical homes, clinical practice improvement, and increased investment in primary and comprehensive care management/coordination services for chronic and other conditions. This shift requires more centralized management of patient needs and extensive care coordination among practitioners and providers, often on a non-face-to-face basis across an

¹ See, for example, <http://content.healthaffairs.org/content/25/5/w378.full>;
<http://www.commonwealthfund.org/publications/issue-briefs/2008/feb/how-disease-burden-influences-medication-patterns-for-medicare-beneficiaries--implications-for-policy>;
<http://www.hhs.gov/ash/about-ash/multiple-chronic-conditions/index.html>;
<http://www.nejm.org/doi/full/10.1056/NEJMp1600999#t=article>;
<https://www.pcpc.org/about>;
<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html>.

extended period of time. In contrast, the current CPT code set is designed with an overall orientation to pay for discrete services and procedural care as opposed to ongoing primary care, care management and coordination, and cognitive services. It includes thousands of separately paid, individual codes, most of which describe highly specialized procedures and diagnostic tests, while there are relatively few codes that describe care management and cognitive services. The term “cognitive services” refers to the type of work that is usually classified and described under the current code set for E/M services, such as the critical thinking involved in data gathering and analysis, planning, management, decision-making, and exercising judgment in ambiguous or uncertain situations.² It is often used to describe PFS services that are not procedural or strictly diagnostic in nature. Further, in the past, we have not recognized as separately payable many existing CPT codes that describe care management and cognitive services, viewing them as bundled and paid as part of other services including the broadly drawn E/M codes that describe face-to-face visits billed by physicians and practitioners in all specialties.

This has resulted in minimal service variation for ongoing primary care, care management and coordination, and cognitive services relative to other PFS services, and in potential misvaluation of E/M services under the PFS (76 FR 42793). Some stakeholders believe that there is substantial misvaluation of physician work within the PFS, and that the current service codes fail to capture the range and intensity of nonprocedural physician activities (E/M services) and the “cognitive” work of certain specialties (<http://www.nejm.org/doi/full/10.1056/NEJMp1600999#t=article>).

Recognizing the inverse for specialties that furnish other kinds of services, MedPAC has noted that the PFS allows some specialties to more easily increase the volume of services they

² <http://www.nejm.org/doi/full/10.1056/NEJMp1600999#t=article>.

provide, and therefore, their revenue from Medicare relative to other specialties, particularly those that spend most of their time providing E/M services. (MedPAC March 2015 Report to the Congress, available at <http://www.medpac.gov/-documents-/reports>). We agree with this analysis, and we recognize that the current set of E/M codes limits Medicare's ability under the PFS to appropriately recognize the relative resource costs of primary care, care management/coordination and cognitive services relative to specialized procedures and diagnostic tests.

In recent years, we have been engaged in an ongoing incremental effort to update and improve the relative value of primary care, care management/coordination, and cognitive services within the PFS by identifying gaps in appropriate payment and coding. These efforts include changes in payment and coding for a broad range of PFS services. This effort is particularly vital in the context of the forthcoming transition to the Quality Payment Program that includes the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) incentives under The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10, enacted April 16, 2015), since MIPS and many APMs will adopt and build on PFS coding, RVUs and PFS payment as their foundation.

In CY 2013, we began by focusing on post-discharge care management and transition of beneficiaries back into the community, establishing new codes to pay separately for transitional care management (TCM) services. Next we finalized new coding and separate payment beginning in CY 2015 for chronic care management (CCM) services provided by clinical staff. In the CY 2016 PFS proposed rule (80 FR 41708 through 41711), we solicited public comments on three additional policy areas of consideration: (1) improving payment for the professional work of care management services through coding that would more accurately describe and

value the work of primary care and other cognitive specialties for complex patients (for example, monthly timed services including care coordination, patient/caregiver education, medication management, assessment and integration of data, care planning); (2) establishing separate payment for collaborative care, particularly, how we might better value and pay for robust inter-professional consultation between primary care physicians and psychiatrists (developing codes to describe and provide payment for the evidence-based psychiatric collaborative care model (CoCM)), and between primary care physicians and other (non-mental health) specialists; and (3) assessing whether current PFS payment for CCM services is adequate and whether we should reduce the administrative burden associated with furnishing and billing these services.

We received substantial feedback on this comment solicitation, which we summarized in the CY 2017 PFS proposed rule and used to develop the following coding and payment proposals for CY 2017 (81 FR 46200 through 46215, and 46263 through 46265):

- Separate payment for existing codes describing prolonged E/M services without direct patient contact by the physician (or other billing practitioner), and increased payment for prolonged E/M services with direct patient contact by the physician (or other billing practitioner) adopting the RUC-recommended values.³
- New coding and payment mechanisms for behavioral health integration (BHI) services including substance use disorder treatment, specifically three codes to describe services furnished as part of the psychiatric CoCM and one code to address other BHI care models.
- Separate payment for complex CCM services, reduced administrative burden for CCM, and an add-on code to the visit during which CCM is initiated (the CCM initiating visit) to

³ “Without direct patient contact” and “with direct patient contact” in this sentence are the terms used in the CPT code descriptor or prefatory language for these prolonged E/M services.

reflect the work of the billing practitioner in assessing the beneficiary and establishing the CCM care plan.

- A new code for cognition and functional assessment and care planning, for treatment of cognitive impairment.
- An adjustment to payment for routine visits furnished to beneficiaries for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lifts, and adjustable padded leg supports) is medically necessary.

We noted that the development of coding for these and other kinds of services across the PFS is typically an iterative process that responds to changes in medical practice and may be best refined over several years, with PFS rulemaking and the development of CPT codes as important parts of that process. We noted with interest that the CPT Editorial Panel and AMA/RUC restructured the former Chronic Care Coordination Workgroup to establish a new Emerging CPT and RUC Issues Workgroup that we hope will continue to consider the issues raised in this section of our CY 2017 proposed rule. At the time of publication of the proposed rule, we were aware that CPT had approved a code to describe assessment and care planning for treatment of cognitive impairment; however, it would not be ready in time for valuation in CY 2017. Therefore, we proposed to make payment using a G-code (G0505⁴) for this service in CY 2017. We were also aware that CPT had approved three codes that describe services furnished consistent with the psychiatric CoCM, but that they would also not be ready in time for valuation in CY 2017. We discuss these services in more detail in the next section of this final rule.

To facilitate separate payment for these services furnished to Medicare beneficiaries during CY 2017, we proposed to make payment through the use of three G-codes (G0502,

⁴ We note that we used placeholder codes (GPPP1, GPPP2, GPPP3, GPPPX, GPPP6, GPPP7, and GDDD1) in the proposed rule. In order to avoid confusion, we have replaced those codes with those that have been finalized as part of the 2017 HCPCS set, even when describing the language in the proposed rule.

G0503, and G0504—see below) that parallel the new CPT codes, as well as a fourth G-code (G0507—see below) to describe services furnished using other models of BHI in the primary care setting. We intended for these to be temporary codes and would consider whether to adopt and establish values for the new CPT codes under our standard process, potentially for CY 2018. We anticipated continuing the multi-year process of implementing initiatives designed to improve payment for, and recognize long-term investment in, primary care, care management and cognitive services, and patient-centered services. While we recognized that there may be some overlap in the patient populations for the proposed new codes, we noted that time spent by a practitioner or clinical staff could not be counted more than once for any code (or assigned to more than one patient), consistent with PFS coding conventions. We expressed continued consideration of additional codes for CCM services that would describe the time of the physician or other billing practitioner. We also expressed interest in whether there should be changes under the PFS to reflect additional models of inter-professional collaboration for health conditions, in addition to those we proposed for BHI.

We proposed to pay under the PFS for services described by new coding as follows (please note that the descriptions included for G0502, G0503, and G0504 are from Current Procedural Terminology (CPT®) Copyright 2016 American Medical Association (and we understand from CPT that they will be effective as part of CPT codes January 1, 2018). All rights reserved):

- G0502: Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements:

- ++ Outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional;
 - ++ Initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan;
 - ++ Review by the psychiatric consultant with modifications of the plan if recommended;
 - ++ Entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant; and
 - ++ Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.
- G0503: Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements:
 - ++ Tracking patient follow-up and progress using the registry, with appropriate documentation;
 - ++ Participation in weekly caseload consultation with the psychiatric consultant;
 - ++ Ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers;
 - ++ Additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant;

++ Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies;

++ Monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment.

- G0504: Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional (List separately in addition to code for primary procedure) (Use G0504 in conjunction with G0502, G0503).

- G0507: Care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional time, per calendar month.

- G0505: Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history obtained from patient and/or caregiver, by the physician or other qualified health care professional in office or other outpatient setting or home or domiciliary or rest home.

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

- G0501: Resource-intensive services for patients for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lifts, and adjustable padded leg supports) is medically necessary and used during the provision of an office/outpatient evaluation and management visit (Add-on code, list separately in addition to primary procedure).

Regarding the majority of these proposals, the public comments were broadly supportive, some viewing our proposals as a temporary solution to an underlying need to revalue E/M services, especially outpatient E/M. Several commenters recommended that CMS utilize the global surgery data collection effort or another major research initiative to distinguish and revalue different kinds of E/M work. The commenters made recommendations about the scope and definition of the proposed services, what types of individuals should be able to provide them, and potential alignment and overlap. The commenters agreed with the need to increase the relative value of primary care, care management and other cognitive care under the PFS and minimize administrative burden for such services, while ensuring value to the program and beneficiaries. The public comments raise or inform a number of issues around how to define and pay for care that is collaborative, integrative or continuous, and we discuss the comments in greater detail below.

2. Non-Face-To-Face Prolonged Evaluation & Management (E/M) Services

In public comments on the CY 2016 PFS proposed rule, many commenters recommended that CMS should establish separate payment for non-face-to-face prolonged E/M service codes that we currently consider to be “bundled” under the PFS (CPT codes 99358, 99359). The CPT descriptors are:

- CPT code 99358 (Prolonged evaluation and management service before and/or after direct patient care, first hour); and
- CPT code 99359 (Prolonged evaluation and management service before and/or after direct patient care, each additional 30 minutes (List separately in addition to code for prolonged service)).

Commenters believed that separate payment for these existing CPT codes would provide a means for physicians and other billing practitioners to receive payment that more appropriately accounts for time that they spend providing non-face-to-face care. We agreed that these codes would provide a means to recognize the additional resource costs of physicians and other billing practitioners, when they spend an extraordinary amount of time outside of an E/M visit performing work that is related to that visit and does not involve direct patient contact (such as extensive medical record review, review of diagnostic test results or other ongoing care management work). We also believed that doing so in the context of the ongoing changes in health care practice to meet the current population's health care needs would be beneficial for Medicare beneficiaries and consistent with our overarching goals related to patient-centered care.

These non-face-to-face prolonged service codes are broadly described (although they include only time spent personally by the physician or other billing practitioner) and have a relatively high time threshold (the time counted must be an hour or more beyond the usual service time for the primary or "companion" E/M code that is also billed). They are not reported for time spent in care plan oversight services or other non-face-to-face services that have more specific codes and no upper time limit in the CPT code set. We believed this made these codes sufficiently distinct from the other codes we proposed for CY 2017 as part of our primary care/cognitive care/care management initiative described in this section of our final rule.

Accordingly, we proposed to recognize CPT codes 99358 and 99359 for separate payment under the PFS beginning in CY 2017. We noted that time could not be counted more than once towards the provision of CPT codes 99358 or 99359 and any other PFS service. We addressed their valuation in the valuation section of the CY 2017 proposed rule.

Through a drafting error, we stated in the proposed rule that we would require these services to be furnished on the same day by the same physician or other billing practitioner as the companion E/M code. We intended to propose conformity with CPT guidance that requires that time counted towards the codes describe services furnished during a single day directly related to a discrete face-to-face service that may be provided on a different day, provided that the services are directly related to those furnished in a face-to-face visit.

We also solicited public comment on our interpretation of existing CPT guidance governing concurrent billing or overlap of CPT codes 99358 and 99359 with complex CCM services (CPT codes 99487 and 99489) and TCM services (CPT codes 99495 and 99496). Specifically CPT provides, “Do not report 99358, 99359 during the same month with 99487-99489. Do not report 99358, 99359 when performed during the service time of codes 99495 or 99496.” Complex CCM services and TCM services are similar to the non-face-to-face prolonged services in that they include substantial non-face-to-face work by the billing physician or other practitioner. The TCM and CCM codes similarly focus on a broader episode of patient care that extends beyond a single day, although they have a monthly service period and the prolonged service codes do not. We sought public input on the intersection of the non-face-to-face prolonged service codes with CCM and TCM services, and with the proposed add-on code to the CCM initiating visit G0506 (Comprehensive assessment of and care planning for patients requiring CCM services). We also solicited comment regarding how distinctions could be made

between time associated with prolonged services and the time bundled into other E/M services, particularly pre- and post-service times, which would continue to be bundled with the other E/M service codes. For all of these services, we expressed concern that there would potentially be program integrity risks as the same or similar non-face-to-face activities could be undertaken to meet the billing requirements for a number of codes. We solicited public comment to help us identify the full extent of program integrity considerations, as well as options for mitigating program integrity risks.

Comment: Many commenters recommended that we adopt the CPT coding provision for CPT codes 99358 and 99359 that allows the prolonged services to be provided on a different day than the companion E/M code. At the same time, several commenters indicated that they request changes to the codes through the established processes of the CPT Editorial Panel. For example, some commenters suggested that CPT codes 99358 and 99359 should be revised so that they have a limited (calendar month) service period or measure shorter time increments (15 minutes). Some commenters recommended that a given physician should not be allowed to report CPT codes 99358 and 99359 for the same beneficiary during the same time he or she reported CCM, TCM, or G0506. These commenters stated that CCM, TCM, and proposed G0506 encompass non-face-to-face care provided to the beneficiary during a given period of time that would be duplicated if the physician is also allowed to report CPT codes 99358 and 99359 during the same time period. Other commenters stated that it would be unusual for G0506 and non-face-to-face prolonged services (CPT codes 99358 and 99359) to be reported for services on the same day, but that both should be allowed if time thresholds are met. To facilitate determination of whether time thresholds are met for various potential code combinations, some commenters recommended that CMS establish a time for G0506 and publish typical times for the companion

codes to the prolonged service codes. This would enable practitioners to determine when they have exceeded “usual” or average times for E/M services and may bill prolonged services. Some commenters recommended that CMS provide tables showing times for E/M visits, CCM, G0506 and prolonged services with specific clinical examples for concurrent billing.

Some commenters believed there might be some overlap between the proposed non-face-to-face prolonged service codes and the post-service work of G0505 (Cognition and functional assessment by the physician or other qualified health care professional in office or other outpatient). Some commenters believed there is a discrepancy between our proposal to allow G0505 to be a companion code to prolonged services, and CPT’s intent that G0505 should only be billed on the same day as another E/M visit if they are unrelated.

MedPAC commented that the companion E/M codes should be revalued instead of providing separate payment for prolonged services associated with the companion codes. However, if we finalize as proposed, MedPAC recommended that we clarify what situations the prolonged codes are appropriate for, beyond average times. Another commenter recommended an alternative policy instead of the non-face-to-face prolonged service codes, namely several modifiers and add-on codes to E/M services, associated with increased work RVUs. A typical time for the primary service would not need to be established. This coding schema would focus on visits actively treating patients with four or more chronic conditions; patients with three or more chronic problems introducing an acute problem during their visit; unexpected abnormal studies; and electronic communication after visits with the patient, lab, and other clinicians. One commenter drew a distinction between prolonged service work and care management services, where care management does not include extensive review of medical records, review of diagnostic tests and further discussion with a caregiver.

Response: We appreciate the comments. First, we had intended to propose to adopt the CPT coding provision for CPT codes 99358 and 99359 that allows the prolonged time to be provided on a different day than the companion E/M code, along with the rest of the CPT prefatory language for these codes. Our final policy will adopt the CPT guidance that allows the prolonged time to be reported for time on a different day than the companion E/M code, along with the rest of the CPT prefatory language for CPT codes 99358 and 99359.

Second, the public comments elucidate that it is difficult to assess potential overlap between prolonged services and many other codes because the included services, service periods and timeframes are not aligned. For example, most services paid under the PFS are valued based on assumptions regarding the typical pre-service, intra-service and post-service time, but do not have required thresholds for time spent. It is difficult to distinguish the times associated with these services from the times for codes that include time requirements in their descriptor. It is also difficult to distinguish the time and other work included in codes that generally describe services furnished during one day (prolonged services and E/M visits) with codes that describe time and work over substantially different service periods (such as the calendar month services like CCM or BHI services) or add-on codes with no pre or post-service time (such as G0506). In addition, because portions of many services are likely describing work that is furnished “incident to” a physician’s or practitioner’s services, the time and effort of the billing practitioner may not be the only relevant time and effort to consider. Moreover, the comments reflect a desire and intent on the part of stakeholders to alter the prolonged service codes in the near future, which would, in turn, alter their intersection with the codes proposed in this section of our 2017 rule and many other codes. The public comments also reflect a lack of consensus regarding

appropriate medical practice and reporting patterns for prolonged services in relation to the services described by the CCM, TCM, proposed G0505 and proposed G0506 codes.

Having considered this feedback, we have decided to finalize our proposal for separate payment of the non-face-to-face prolonged service codes (CPT 99358, 99359) and adopt the CPT code descriptors and prefatory language for reporting these services. We stress that we intend these codes to be used to report extended non-face-to-face time that is spent by the billing physician or other practitioner (not clinical staff) that is not within the scope of practice of clinical staff, and that is not adequately identified or valued under existing codes or the 2017 finalized new codes. We appreciate the commenters' suggestion to display the typical times associated with relevant services. We have posted a file that notes the times assumed to be typical for purposes of PFS rate-setting. That file is available on our website under downloads for the CY 2017 PFS final rule at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>. We note that while these typical times are not required to bill the displayed codes, we would expect that only time spent in excess of these times would be reported under a non-face-to-face prolonged service code.

Based on our analysis of comments, we do not believe there is significant overlap between CPT codes 99358 and 99359 and the CCM codes (CPT 99487, 99489, 99490) or our finalized BHI service codes (G0502, G0503, G0504, G0507 discussed below). The work of the billing practitioner in the provision of non-complex CCM and the BHI services is related to the direction of ongoing care management and coordination activities of other individuals, compared to the work of 99358 and 99359 which is described as personally performed and directly related to a face-to-face service. On that basis, we do not believe that there is significant overlap in the description of services or the valuation.

The potential intersection of CPT codes 99358 and 99359 with the complex CCM codes is harder to assess because complex CCM explicitly includes medical decision-making of moderate to high complexity by the billing practitioner, which is not performed by clinical staff. The complex CCM codes, however, only measure or count the time of clinical staff. Similarly, TCM includes moderate to high complexity medical decision-making during the service period as well as a level 4 or 5 face-to-face visit, even though clinical staff may perform a number of other aspects of the service. For CY 2017, for administrative simplicity, we are adopting the CPT provision (and finalizing as proposed) that complex CCM cannot be reported during the same month as non-face-to-face prolonged services, CPT codes 99358 and 99359 (by a single practitioner). Similarly, we are adopting the CPT provision that non-face-to-face prolonged services, CPT codes 99358 and 99359 may not be reported when performed during the service time of TCM (CPT codes 99495 and 99496) (by a single practitioner). We interpret the CPT provision to mean that CPT codes 99358 and 99359 cannot be reported during the TCM 30-day service period, by the same practitioner who is reporting the TCM.

Regarding potential intersection of CPT codes 99358 and 99359 with proposed G0505 (Cognition and functional assessment by the physician or other qualified health care professional in office or other outpatient), we are finalizing our proposal that G0505 be designated as a companion or “base” E/M code to non-face-to-face prolonged services (CPT codes 99358 and 99359) (see section II.E.5 for a detailed discussion of G0505). That is, for CY 2017 CPT codes 99358 and 99359 may be reported with G0505 as the associated companion code, whether furnished on the same day or a different day. We believe CPT intended the code on which G0505 is modeled to function like a specific E/M service, and that while the specificity of the service explicitly includes care planning unique to the needs of patients with particular

conditions, there may well be circumstances where the pre- or post-time for a particular beneficiary may be prolonged. In their current form, the non-face-to-face prolonged service codes exist for the purpose of providing additional payment to account for the biller's additional time related to E/M visits. Therefore, we believe the non-face-to-face prolonged service codes should be reportable when related to E/M services, including those such as G0505 that describe more specific E/M work. We look forward to continued feedback on this issue, including through potential revisions to CPT guidance.

Regarding intersection of CPT codes 99358 and 99359 with G0506, we note that G0506 is already an add-on code to another E/M service (the CCM initiating visit, which can be the AWW/IPPE or a qualifying face-to-face E/M visit). We are providing in section II.E.4.a that at this time (beginning in CY 2017), G0506 will be a code that is only billable one time, at the outset of CCM services. We agree with commenters that it would be unusual for physicians to spend enough time with a given beneficiary on a given day to warrant reporting all three codes (the initiating visit code, G0506, and a prolonged service code). We also believe that a simpler approach is preferable at this time (two related codes for CCM initiation, instead of possibly three). Therefore our final policy for CY 2017 is that prolonged services (whether face-to-face or non-face-to-face) cannot be reported in addition to G0506 in association with a companion E/M code that also qualifies as the CCM initiating visit. In association with the CCM initiating visit, a billing practitioner may choose to report either prolonged services or G0506 (if requirements to bill both prolonged services and G0506 are met), but cannot report both a prolonged service code and G0506.

3. Establishing Separate Payment for Behavioral Health Integration (BHI)

In the CY 2016 PFS final rule with comment period (80 FR 70920), we stated that we believe the care and management for Medicare beneficiaries with behavioral health conditions often requires extensive discussion, information-sharing and planning between a primary care physician and a specialist. In CY 2016 rulemaking, we described that in recent years, many randomized controlled trials have established an evidence base for an approach to caring for patients with behavioral health conditions called the psychiatric Collaborative Care Model (CoCM). We sought information to assist us in considering refinements to coding and payment to address this model in particular. The psychiatric CoCM is one of many models for behavioral health integration or BHI, a term that refers broadly to collaborative care that integrates behavioral health services principally with primary care, but that may also integrate behavioral health care with inpatient and other clinical care. BHI is a team-based approach to care that focuses on integrative treatment of patients with medical and mental or behavioral health conditions. In the CY 2017 proposed rule (81 FR 46203 through 46205), we proposed four new G-codes for BHI services: three describing the psychiatric CoCM specifically, and one generally describing related models of care.

a. Psychiatric Collaborative Care Model (CoCM)

A specific model for BHI, psychiatric CoCM typically is provided by a primary care team consisting of a primary care provider and a care manager who works in collaboration with a psychiatric consultant, such as a psychiatrist. Care is directed by the primary care team and includes structured care management with regular assessments of clinical status using validated tools and modification of treatment as appropriate. The psychiatric consultant provides regular consultations to the primary care team to review the clinical status and care of patients and to make recommendations. As we previously noted, several resources have been published that

describe the psychiatric CoCM in greater detail and assess the impact of the model, including pieces from the University of Washington (<http://aims.uw.edu/>), the Institute for Clinical and Economic Review (<http://icer-review.org/announcements/icer-report-presents-evidence-based-guidance-to-support-integration-of-behavioral-health-into-primary-care/>), and the Cochrane Collaboration (http://www.cochrane.org/CD006525/DEPRESSN_collaborative-care-forpeople-with-depression-and-anxiety). Because this particular kind of collaborative care model has been tested and documented in medical literature, in the CY 2016 proposed rule we expressed particular interest in how coding used to describe PFS services might facilitate appropriate valuation of the services furnished under this model. We solicited public comments to assist us in considering refinements to coding and payment to address this model in particular relative to current coding and payment policies, as well as information related to various requirements and aspects of these services.

After consideration of the comments, we proposed in the CY 2017 PFS proposed rule to begin making separate payment for services furnished using the psychiatric CoCM, beginning January 1, 2017. We were aware that the CPT Editorial Panel, recognizing the need for new coding for services under this model of care, had approved three codes to describe the psychiatric collaborative care that is consistent with this model, but the codes would not be ready in time for valuation in CY 2017. Current CPT coding does not accurately describe or facilitate appropriate payment for the treatment of Medicare beneficiaries under this model of care. For example, under current Medicare payment policy, there is no payment made specifically for regular monitoring of patients using validated clinical rating scales or for regular psychiatric caseload review and consultation that does not involve face-to-face contact with the patient. We believed that these resources are directly involved in furnishing ongoing care management services to

specific patients with specific needs, but they are not appropriately recognized under current coding and payment mechanisms. Because PFS valuation is based on the relative resource costs of the PFS services furnished to Medicare beneficiaries, we believed that appropriate coding for these services for CY 2017 will facilitate accurate payment for these and other PFS services. Therefore, we proposed separate payment for services under the psychiatric CoCM using three new G-codes, as detailed below: G0502, G0503, and G0504, which would parallel the CPT codes that are being created to report these services.

The proposed code descriptors were as follows (from Current Procedural Terminology (CPT®) Copyright 2016 American Medical Association (and we understand from CPT that they will be effective as part of CPT codes January 1, 2018). All rights reserved):

- G0502: Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements:

- ++ Outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional;

- ++ Initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan;

- ++ Review by the psychiatric consultant with modifications of the plan if recommended;

- ++ Entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant; and

++ Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.

- G0503: Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements:

- ++ Tracking patient follow-up and progress using the registry, with appropriate documentation;

- ++ Participation in weekly caseload consultation with the psychiatric consultant;

- ++ Ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers;

- ++ Additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant;

- ++ Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies;

- ++ Monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment.

- G0504: Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other

qualified health care professional (List separately in addition to code for primary procedure)
(Use G0504 in conjunction with G0502, G0503).

We stated that we intend these to be temporary codes and would consider whether to adopt and establish values for the associated new CPT codes under our standard process once those codes are active.

We proposed that these services would be furnished under the direction of a treating physician or other qualified health care professional during a calendar month. These services would be furnished when a patient has a diagnosed psychiatric disorder that requires a behavioral health care assessment; establishing, implementing, revising, or monitoring a care plan; and provision of brief interventions. The diagnosis could be either pre-existing or made by the billing practitioner. These services would be reported by the treating physician or other qualified health care professional and include the services of the treating physician or other qualified health care professional, the behavioral health care manager (see description below) who would furnish services incident to services of the treating physician or other qualified health care professional, and the psychiatric consultant (see description below) whose consultative services would be furnished incident to services of the treating physician or other qualified health care professional. We proposed that beneficiaries who are appropriate candidates for care reported using the psychiatric CoCM codes could have newly diagnosed conditions, need help in engaging in treatment, have not responded to standard care delivered in a non-psychiatric setting, or require further assessment and engagement prior to consideration of referral to a psychiatric care setting. Beneficiaries would be treated for an episode of care, defined as beginning when the behavioral health care manager engages in care of the beneficiary under the appropriate supervision of the billing practitioner and ending with:

- The attainment of targeted treatment goals, which typically results in the discontinuation of care management services and continuation of usual follow-up with the treating physician or other qualified healthcare professional; or
- Failure to attain targeted treatment goals culminating in referral to a psychiatric care provider for ongoing treatment; or
- Lack of continued engagement with no psychiatric collaborative care management services provided over a consecutive 6-month calendar period (break in episode).

A new episode of care would start after a break in episode of 6 calendar months or more.

The treating physician or other qualified health care professional would direct the behavioral health care manager and continue to oversee the beneficiary's care, including prescribing medications, providing treatments for medical conditions, and making referrals to specialty care when needed. Medically necessary E/M and other services could be reported separately by the treating physician or other qualified health care professional, or other physicians or practitioners, during the same calendar month. Time spent by the treating physician or other qualified health care professional on activities for services reported separately could not be included in the services reported using G0502, G0503, and G0504. We proposed that the behavioral health care manager would be a member of the treating physician or other qualified health care professional's clinical staff with formal education or specialized training in behavioral health (which could include a range of disciplines, for example, social work, nursing, and psychology) who provides care management services, as well as an assessment of needs, including the administration of validated rating scales⁵, the development of a care plan, provision of brief interventions, ongoing collaboration with the treating physician or other qualified health

⁵ For example, see <https://aims.uw.edu/resource-library/measurement-based-treatment-target>.

care professional, maintenance of a registry⁶, all in consultation with a psychiatric consultant. The behavioral health care manager would furnish these services both face-to-face and non-face-to-face, and consult with the psychiatric consultant minimally on a weekly basis. We proposed that the behavioral health care manager would be on-site at the location where the treating physician or other qualified health care professional furnishes services to the beneficiary.

We proposed that the behavioral health care manager may or may not be a professional who meets all the requirements to independently furnish and report services to Medicare. If otherwise eligible, then that individual could report separate services furnished to a beneficiary receiving the services described by G0502, G0503, G0504, and G0507 in the same calendar month. These could include: psychiatric evaluation (90791, 90792), psychotherapy (90832, 90833, 90834, 90836, 90837, 90838), psychotherapy for crisis (90839, 90840), family psychotherapy (90846, 90847), multiple family group psychotherapy (90849), group psychotherapy (90853), smoking and tobacco use cessation counseling (99406, 90407), and alcohol or substance abuse intervention services (G0396, G0397). Time spent by the behavioral health care manager on activities for services reported separately could not be included in the services reported using time applied to G0502, G0503, and G0504.

The psychiatric consultant involved in the “incident to” care furnished under this model would be a medical professional trained in psychiatry and qualified to prescribe the full range of medications. The psychiatric consultant would advise and make recommendations, as needed, for psychiatric and other medical care, including psychiatric and other medical diagnoses, treatment strategies including appropriate therapies, medication management, medical management of complications associated

⁶ For example, see <https://aims.uw.edu/collaborative-care/implementation-guide/plan-clinical-practice-change/identify-population-based>.

with treatment of psychiatric disorders, and referral for specialty services, that are communicated to the treating physician or other qualified health care professional, typically through the behavioral health care manager. The psychiatric consultant would not typically see the patient or prescribe medications, except in rare circumstances, but could and should facilitate a referral to a psychiatric care provider when clinically indicated.

In the event that the psychiatric consultant furnished services to the beneficiary directly in the calendar month described by other codes, such as E/M services or psychiatric evaluation (CPT codes 90791 and 90792), those services could be reported separately by the psychiatric consultant. Time spent by the psychiatric consultant on activities for services reported separately could not be included in the services reported using G0502, G0503, and G0504.

We also noted that, although the psychiatric CoCM has been studied extensively in the setting of specific behavioral health conditions (for example, depression), we received persuasive comments in response to the CY 2016 proposed rule recommending that we not specify particular diagnoses required for use of the codes for several reasons, including that: there may be overlap in behavioral health conditions; there are concerns that there could be modification of diagnoses to fit within payment rules which could skew the accuracy of submitted diagnosis code data; and for many patients for whom specialty care is not available, or who choose for other reasons to remain in primary care, primary care treatment will be more effective if it is provided within a model of integrated care that includes care management and psychiatric consultation.

Comment: The public comments were very supportive of our creation of the three G-codes for CY 2017 to pay for services furnished using the psychiatric CoCM. The commenters offered a number of recommendations regarding valuation of the codes. Some commenters requested additional codes, sought clarification, or presented statements in favor of including the services of practitioners other than psychiatrists, especially psychologists and social workers, within the proposed codes.

Response: We thank the commenters for their support of coding and valuation for services furnished using the psychiatric CoCM, and for their recommendations regarding appropriate valuation. We address the comments on valuation in section II.L of this final rule. We address the comments regarding payment for services of psychologists and social workers below.

Comment: Several commenters expressed concern that making separate payment for psychiatric CoCM for the treatment of mood disorders might result in neglecting treatment for other mental health conditions. Other commenters expressed support for not designating a limited set of eligible behavioral health diagnoses. One commenter stated that requiring a diagnosed behavioral health condition might mean that subclinical issues or undiagnosed behavioral health conditions would be neglected.

Response: We continue to believe that we should not limit billing and payment for the psychiatric CoCM codes to a limited set of behavioral health conditions. As we understand it, the psychiatric CoCM model of care may be used to treat patients with any behavioral health condition that is being treated by the billing practitioner, including substance use disorders. In the Collaborative Care literature reviewed by the Cochrane Collaboration and others, there is stronger evidence of effectiveness and cost-effectiveness for certain behavioral

disorders, particularly mood and anxiety disorders, than for others. However, we continue to receive persuasive comments indicating that the psychiatric CoCM is recommended for broader incorporation into clinical practice, and recommending that we not specify the use of the psychiatric CoCM codes for only particular behavioral health diagnoses. Therefore we are not limiting billing and payment for the psychiatric CoCM codes to a specified set of behavioral health conditions.

In response to the public comment regarding whether we should require a diagnosed psychiatric disorder (as opposed to a subclinical or undiagnosed condition), we are clarifying that as described, the services require that there must be a presenting psychiatric or behavioral health condition(s) that, in the clinical judgment of the treating physician or other qualified health professional, warrants “referral” to the behavioral health care manager for further assessment and treatment through provision of psychiatric CoCM services. “Referral” is placed in quotes because the behavioral health care manager may be located in the same practice as the treating physician or other qualified health professional, who in any event provides ongoing oversight and continues to treat the beneficiary. However, the referring diagnosis (or diagnoses) may be either pre-existing or made by the treating physician or other qualified health professional, and we are not establishing any specific list of eligible or included diagnoses or conditions. The treating physician or other qualified health professional may not be qualified or able to fully diagnose all relevant psychiatric or behavioral health condition(s) prior to referring the beneficiary for psychiatric CoCM services. If in the course of providing psychiatric CoCM services, it becomes clear that the referring condition(s) or other diagnoses cannot be addressed by psychiatric CoCM services, then we understand that the beneficiary

should be referred for other psychiatric treatment or should continue usual follow-up care with the treating practitioner, because the episode of psychiatric CoCM services ends if there is failure to attain targeted treatment goals after or despite changes in treatment, as indicated. Beneficiaries receiving care reported using the psychiatric CoCM codes may, but are not required to have comorbid chronic or other medical condition(s) that are being managed by the treating practitioner.

Comment: Several commenters who supported payment for the proposed codes for psychiatric CoCM services in primary care settings, raised questions about whether these codes could be used to bill for services furnished in other settings that are not traditional primary care settings, such as inpatient or long-term care, oncology practices, or emergency departments. Some of these commenters recommended additional new codes to pay for services furnished in these other settings.

Response: The psychiatric CoCM trials and real world implementation have mainly included primary care practice that broadly includes pediatrics, obstetrics/gynecology, and geriatrics as well as family practice and general internal medicine. The psychiatric CoCM has also been used in cardiology and oncology practice, and we believe it could be used in various medical specialty settings, as long as the specialist physician or practitioner is managing the beneficiary's behavioral health condition(s) as well as other medical conditions (for example, cancer, status-post acute myocardial infarction and other conditions where co-morbid depression is common). Accordingly, we are not limiting the code to reporting by only "traditional" primary care specialties. We believe primary care practitioners will most frequently perform the services described by the new psychiatric CoCM codes, but if other specialist

practitioners perform these services and meet all of the requirements to bill the code(s), then they may report the psychiatric CoCM codes. We are interested in receiving additional, more specific information from stakeholders regarding which specialties furnish psychiatric CoCM services. We note that we would generally not expect psychiatrists to bill the psychiatric CoCM codes, because psychiatric work is defined as a sub-component of the psychiatric CoCM codes.

Regarding psychiatric CoCM services furnished to inpatients or beneficiaries in long-term care settings such as nursing or custodial care facilities, we note that the forthcoming CPT codes are not limited to office or other outpatient or domiciliary services. Moreover, our goal is to separately identify and pay for psychiatric CoCM services furnished to beneficiaries in any appropriate setting of care, whether inpatient or outpatient, in recognition of the associated time and service complexity. Care of beneficiaries who are admitted to a facility, are in long-term care, or are transitioning among settings during the month may be more complex than the care of other types of patients. While there is some overlap between psychiatric CoCM and CCM services, they are distinct services with differing patient populations, as discussed elsewhere in this section of our final rule. Therefore, we have valued the psychiatric CoCM services in both facility and non-facility settings (see section I.L. on valuation). We are not limiting the time that can be counted towards the monthly time requirement to bill the psychiatric CoCM code(s) to time that is spent in the care of an outpatient or a beneficiary residing in the community. However, we also stress that G0502, G0503 and G0504 can only be reported by a treating physician or other qualified health care professional when he or she has directed the psychiatric CoCM service for the duration of time that he or she is

reporting it, and has a qualifying relationship with individuals providing the service under his or her direction and control. Also, time and effort that is spent managing care transitions for CCM or TCM patients and that is counted towards reporting TCM or CCM services, cannot also be counted towards reporting any transitional care management activities reported under a BHI service code(s), either the psychiatric CoCM codes or the code describing other BHI services. We welcome additional input from stakeholders regarding appropriate (or inappropriate) sites of service for G0502, G0503 and G0504.

We note that for CY 2017, the facility PE RVU for psychiatric CoCM services will include the indirect PE allocated based on the work RVUs, but no direct PE (which is explicitly comprised of other labor, equipment and supplies). This is because historically, the PFS facility rate for a given professional service assumes that the billing practitioner is not bearing a significant resource cost in labor by other individuals, equipment or supplies. We generally assume that those costs are instead borne by the facility, and are adequately accounted for in a separate payment made to the facility to account for these costs and other costs incurred by the facility for the beneficiary's facility stay. For BHI services and similar care management services such as CCM, we have been considering whether this approach to PFS valuation is optimal because the PFS service, in significant part, may be provided by the behavioral health care manager, clinical staff, or even other physicians under the employment of the billing practitioner or under contract to the billing practitioner. These individuals may provide much of the PFS service remotely, and are not necessarily employees or staff of the facility. Indeed, the BHI services are defined in terms of activities performed by individual(s) other than the billing practitioner and who may not be affiliated with or located within the facility, even though as we discuss below the billing practitioner must also perform certain work. For this type of PFS

service, there may be more direct practice expense borne by the billing practitioner even though the beneficiary is located, for part or all of the month, in a facility receiving institutional payment. We plan to consider these issues further in the future.

Comment: One specialty association supported the proposed psychiatric CoCM codes, noting that although few of their members would use these codes, they set an important precedent to recognize interdisciplinary care that requires significant non-face-to-face work. This commenter anticipated that similar code series may be developed in the future to describe complex management in other specialties including neurology, and supported the adoption of language approved at CPT that carefully defined the roles of multiple professionals. Other commenters similarly expressed support for separate payment for additional collaborative care services, including inter-professional consultation in the treatment of other illnesses such as cancer or multiple sclerosis.

Response: We continue to be interested in new coding that describes integrative, collaborative or consultative care among specialties other than primary care and behavioral health/psychiatry. We are especially interested in new coding that describes such care in sufficient detail that distinguishes it from existing service codes, and that would further the appropriate valuation of cognitive services. We will continue to follow any new coding proposals at CPT relevant for the Medicare population. We note that we have followed CPT's lead in finalizing proposed code G0505 for cognitive impairment assessment and care planning (see section II.E.5) as well as for psychiatric CoCM services. BHI is a unique type of service that we believe until now has not been well identified nor appropriately valued under existing codes. BHI is not comprised of mere consultation among professionals and has a unique evidence base, in addition to being

recently addressed by forthcoming CPT coding. In addition, given the shortage of available psychiatric and other mental health professionals in many parts of the country, we believe it is important to identify and make accurate payment for models of care that facilitate access to psychiatric and other behavioral health specialty care through innovations in medical practice, like the ones described by these codes..

Comment: One commenter asked CMS to clarify inclusion of nurse practitioners who are primary care practitioners and, in the specialty of psychiatry, psychiatric nurse practitioners who can perform psychiatric evaluations and treat psychiatric problems.

Response: Nurse practitioners are authorized to independently bill Medicare for their services, and can also bill Medicare for services furnished incident to their services. Therefore, nurse practitioners who furnish the psychiatric CoCM services as described may bill for the psychiatric CoCM codes. Nurse practitioners who meet our final qualifications to serve as the behavioral health care manager may provide the behavioral health care manager services incident to the services of another (billing) practitioner. Nurse practitioners who meet all of our final requirements to serve as the psychiatric consultant may provide the psychiatric consultant services incident to the services of the billing practitioner.

Comment: Regarding the care planning requirements for psychiatric CoCM services, some commenters noted that there is not necessarily value in accumulating or enumerating a number of different types of care plans addressing different aspects of the beneficiary's problems, such as a behavioral or psychiatric care plan, a CCM care plan, and a cognitive impairment care plan (see G0505 in section II.E.5).

Response: While the proposed descriptors for the psychiatric CoCM services referred to an “individualized treatment plan,” not a “care plan,” we proposed in addition that the behavioral health care manager would “develop a care plan.” While any care planning should take into account the whole patient, our intent is that the care planning included in the CCM coding (and G0506, the CCM initiating visit add-on code) will be the most comprehensive in nature, addressing all health issues with particular focus on the multiple chronic conditions being managed by the billing practitioner. In that sense, the CCM care plan is an integrative care plan incorporating more comprehensive health information on all of the beneficiary’s health issues, or reconciling care plans of other practitioners. In contrast, the BHI care planning will focus on behavioral health or psychiatric issues, in particular, just as cognitive impairment care planning will focus on cognitive impairment issues, in particular (see section II.E.5). We are not requiring the psychiatric CoCM treating practitioner or behavioral health consultant to perform care planning that incorporates comprehensive health information on all of the beneficiary’s health issues or reconciles the care plans of other practitioners, as would be expected for CCM care planning.

We understand that adoption of EHRs may be lower among behavioral health practitioners⁷ and note that resources are available to help inform how care plans can support team-based care and BHI.⁸ Our understanding from the public comments last year and subsequent discussions with experts on the psychiatric CoCM model of care, is that no specific electronic technology or format is necessary or indispensable to carry out

⁷ See for instance <http://dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php> and <https://www.thenationalcouncil.org/wp-content/uploads/2012/10/HIT-Survey-Full-Report.pdf>.

⁸ For instance, AHRQ has a variety of resources on how shared care plans can support team-based care and behavioral health integration at <https://integrationacademy.ahrq.gov/playbook/develop-shared-care-plan>

the psychiatric CoCM model of care, or perform the services included in the codes we are creating to describe the services furnished using that model. We believe the format of the behavioral health care plan (or any care plan) is less important than having a process whereby feedback and expertise from all relevant practitioners and providers, whether internal or external to the billing practice, are integrated into the beneficiary's treatment plan and goals; that this plan be regularly assessed and revisited by the practitioner who is assuming an overall care management role for the beneficiary in a given month; that the patient is engaged in the care planning process; and that the care planning be documented in the medical record (as with any required element of any PFS service). We are revising the requirement for care planning by the behavioral health care manager accordingly, that he or she will perform "behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes."

Comment: A number of commenters recommended that we should not require the behavioral health care manager for the psychiatric CoCM services to be located on site within the primary care practice. The commenters noted that in some settings, particularly rural areas or smaller practices, this may be especially important. Some commenters assumed that there is also a behavioral health care manager for G0507 (discussed below). These commenters compared BHI services (the psychiatric CoCM services and G0507) to CCM and recommended that CMS adopt the same requirements for all the BHI codes as for CCM, regarding supervision, location of a behavioral health care manager, and third party outsourcing.

Response: For the psychiatric CoCM services, we proposed that the behavioral health care manager would be a member of the treating physician or other qualified health care professional's clinical staff, and would be required to be located on site but able to work under general supervision. In addition, we proposed that the behavioral health care manager provides his or her services both face-to-face and non-face-to-face. We believed that services provided using the psychiatric CoCM model of care commonly involve face-to-face interaction between the behavioral health care manager and the beneficiary on appropriate occasions, such as the outset of services (a "warm hand-off" from the treating physician or other qualified health care professional). In addition, whether face-to-face or non-face-to-face, many of the included behavioral health care manager duties could be performed while the treating practitioner is not in the office and could be performed after hours. We note that the behavioral health care manager duties are listed in full above, and include care management services, as well as an assessment of needs, including the administration of validated rating scales, behavioral health care planning, provision of brief interventions, ongoing collaboration with the treating physician or other qualified health care professional, and maintenance of a registry, all in consultation with a psychiatric consultant.

The delivery of the psychiatric CoCM depends, in part, on continuity of care between a given patient and the assigned behavioral health care manager. Also it requires collaboration, integration and ongoing data flow between the behavioral health care manager and the treating practitioner the behavioral health care manager is supporting, as well as with the psychiatric consultant who is usually remotely located under the psychiatric CoCM model of care. As previously discussed, the psychiatric

CoCM is an integrative model of care, and in considering our proposal we were concerned that allowing the behavioral health care manager to be located remotely would compromise their ability to collaborate, communicate, and timely treat and share information with the beneficiary and the rest of the care team. We are aware of many care management companies and health information technology companies that may seek to provide remote care management and related services under all of the new BHI codes, as they have for CCM and similar services recently adopted under the PFS. We received public comments from several such stakeholders that indicated an interest in the provision of BHI services and related health information technology. We understand that there have been successful implementations (positive randomized controlled trials) of the psychiatric CoCM using remote call centers; however, in these implementations, call center staff were not randomly rotated among patients and there was ongoing data flow and connectivity between the behavioral health care manager and the other members of the care team, as well as the patient. Moreover, the behavioral health care manager would presumably have to be on site at least some of the time (even if under general supervision), in order to provide some of their services in-person with the beneficiary.

The fact that we proposed and are finalizing general supervision for the psychiatric CoCM codes as we did for CCM services (see section II.E.3.b) does not mean that general supervision alone suffices to meet the requirements of the psychiatric CoCM for continuity, collaboration and integration among the care team members, including the beneficiary. General supervision means that the service is furnished under the overall direction and control of the practitioner billing the service, but without the presence of the practitioner being required during the performance of the service. This definition

does not directly govern where individual(s) providing the service on an incident to basis are located, whether on site or remote. Rather, it governs the location and informs the involvement of the billing practitioner.

For payment purposes, we are assigning general supervision to the psychiatric CoCM codes because we do not believe it is clinically necessary that the professionals on the team who provide services other than the treating practitioner (namely, the behavioral health care manager and the psychiatric consultant) must have the billing practitioner immediately available to them at all times, as would be required under a higher level of supervision. However, general supervision sets the minimum standard for supervision and does not, by itself, meet the requirements we are setting for billing new codes G0502, G0503 and G0504. While certain aspects of psychiatric CoCM services might be furnished under general supervision, we do not believe the general supervision requirement adequately describes the nature of the relationship and interactions of the respective team members for services furnished using the psychiatric CoCM or the codes we are creating to describe those services. Moreover it only directly addresses the physical location of the billing practitioner, not the behavioral health care manager, necessarily.

After considering the public comments, we are not finalizing our proposal that the behavioral health care manager must be a member of the treating physician or other qualified health care professional's clinical staff. As some of the psychiatric CoCM services can be contracted out to a third party (subject to rules discussed below), the contracted individuals are not necessarily employees of the treating practitioner.

Regarding the face-to-face provision of services by the behavioral health care manager, we are requiring that the behavioral health care manager must be available to provide services on a face-to-face basis, but not that face-to-face services must be provided. We are not finalizing the proposed requirement that the behavioral health care manager must be located on site, in order to allow for after-hours or appropriate remote provision of services. However, to ensure clinical integration with the treating practitioner and familiarity and continuity with the beneficiary, which are characteristic of services furnished under the psychiatric CoCM model of care, we are requiring that the behavioral health care manager must have a collaborative, integrated relationship with the rest of the care team members, and be able to perform all of the required elements of the psychiatric CoCM services delineated for the behavioral health care manager. The behavioral health care manager must have the ability to engage the beneficiary outside of regular clinic hours as necessary to perform their duties under the CoCM model, and have a continuous relationship with the beneficiary. This does not mean the behavioral health care manager is necessarily an employee of or always physically located within the practice, nor does it require provision of behavioral health care manager services to the beneficiary on site. The behavioral health care manager may provide his or her services from a remote location that is remote from the billing practitioner or remote from the beneficiary, subject to incident to rules and regulations in 42 CFR 410.26, if he or she has a qualifying relationship with the rest of the care team including the beneficiary, and is available to provide services face-to-face.

We will monitor this issue going forward, not just for the psychiatric CoCM but also for the general BHI service code (G0507) we are finalizing, as well as for TCM and

CCM services. As we discuss in the final rule section on CCM below, we are continuing to consider whether outsourcing certain aspects of these services to a third party fragments care, leads to insufficient involvement and oversight of the billing practitioner or results in services that do not actually represent or facilitate continuous, seamless transitional care and other required aspects of these services. We will continue to consider how to best define the continuity of care that is required for services furnished and billed under all of these codes, and whether arrangements for remote provision of services whether by a case management company or another entity increases rather than reduces service fragmentation. Advances in health information technology provide opportunities for remote connectivity and interoperability that may assist and be useful, if not necessary, for reducing care fragmentation. However, 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 note that while time spent by the treating practitioner is not explicitly counted for in codes G0502, G0503 and G0504, these codes are valued to include work performed directly by the treating practitioner. The treating practitioner directs the behavioral health care manager and continues to oversee the patient's care, including prescribing medications, providing treatments for medical conditions, and making referrals to specialty care when needed. We are finalizing as proposed that some of these services may be separately billable. However, we wish to emphasize that the treating practitioner must remain involved in ongoing oversight, management, collaboration and reassessment as appropriate to bill the psychiatric CoCM codes.

Comment: We received a number of comments requesting that we allow or recognize pharmacists, especially neurologic or psychiatric pharmacists, or doctoral-level clinical psychologists to serve as the psychiatric consultant. Some commenters were concerned that CMS is advocating pharmacotherapy over psychotherapy by requiring a psychiatric consultant who can prescribe medication.

Response: We agree with the commenters that there are multiple types of indicated treatment for behavioral health conditions, including psychotherapy and other psychosocial interventions as well as pharmacotherapy that are available and should be offered to beneficiaries receiving psychiatric CoCM services. Our intent is not to inappropriately steer beneficiaries into medication-based treatment, but rather that the psychiatric consultant be able to present and recommend the full range of treatment options including but not limited to medications, and to advise regarding any medications the beneficiary chooses to take. Under the psychiatric CoCM, the psychiatric consultant must be able to prescribe medication. As we discuss in section II.L on valuation of G0502, G0503 and G0504, we agree with the commenters who stated that the role of the psychiatric consultant under these codes is primarily evaluation and management, which is not within the scope of pharmacists or clinical psychologists under Medicare rules. Therefore, we are finalizing the role and qualifications of the psychiatric consultant as proposed. The general BHI code (G0507), which we are finalizing, was intended and may be used to report other models of care, where the beneficiary may not receive E/M services from the consultant and the consultant may only be authorized to provide psychotherapy or consultation regarding medications (see section II.E.3.b).

Comment: We received a number of comments recommending various types of professionals as qualified to serve as the behavioral health care manager, such as licensed clinical social workers (LCSWs) and psychologists.

Response: Unlike CCM and the general BHI service (code G0507), the psychiatric CoCM codes are used to report time that is spent in specified activities performed by a behavioral health care manager having formal education or specialized training in those activities, whether or not the behavioral health care manager is eligible to directly bill Medicare for other services. The behavioral health care manager may or may not be a professional who meets all the requirements to independently furnish and report services to Medicare. The behavioral health care manager must also meet any applicable licensure and state law requirements, which is required under 42 CFR 410.26 for all services provided under the PFS. LCSWs would meet these requirements, as would qualified registered nurses, clinical psychologists and other qualified clinical staff. Time spent by administrative or clerical staff cannot be counted towards the time required to bill G0502, G0503 or G0504.

Evaluation and management services (such as face-to-face E/M visits) may be separately billed during the service period or on the same day as the psychiatric CoCM services, provided time is not counted twice towards the same code.

b. General Behavioral Health Integration (BHI)

We recognize that the psychiatric CoCM is prescriptive and that much of its demonstrated success may be attributable to adherence to a set of elements and guidelines of care. We are finalizing the code set discussed above to pay accurately for care furnished using this specific model of care, given its widespread adoption and recognized effectiveness. However, we note that PFS coding, in general, does not dictate how physicians practice medicine

and believe that it should, instead, reflect the practice of medicine. We also recognize that there are primary care practices that are incurring, or may incur, resource costs inherent to treatment of patients with similar conditions based on BHI models of care other than the psychiatric CoCM that may benefit beneficiaries with behavioral health conditions (see, for example, the approaches described at <http://www.integration.samhsa.gov/integrated-care-models>). There are a variety of care models ranging from behavioral health professionals embedded within a primary care office for same-day treatment, to remote consultation, to assessment-and-referral (see, for example, <http://www.commonwealthfund.org/publications/newsletters/quality-matters/2014/august-september/profiles>; and <http://www.integration.samhsa.gov/integrated-care-models>). These models of care have tended to arise from clinical practice as opposed to the research environment (<http://psychnews.psychiatryonline.org/doi/full/10.1176/appi.pn.2014.10b25>), and include resource costs that differ in various respects from those associated with the psychiatric CoCM.

To recognize the resource costs associated with furnishing such BHI services to Medicare beneficiaries, we also proposed to make payment using a new G-code that describes care management for beneficiaries with behavioral health conditions under other models of care. We believe that the resources associated with such care are not currently adequately recognized under the PFS. The proposed code was G0507 (Care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional, per calendar month). We noted that we would expect this code to be refined over time as we receive more information about other BHI models being used and how they are implemented.

We sought stakeholder input on whether we should consider different increments of time for this code, such as a base code plus an add-on code comprised of additional 20 minute increments. We recognized that BHI services furnished under the proposed code may range in resource costs. We believed that appropriate payment for these services would further the refinement and implementation of BHI models of care, and that having utilization data would inform future refinement of the proposed code's valuation.

Comment: The commenters were supportive of new coding to support payment for other BHI models of care. They believed G0507 could be used by some smaller or medium sized practices who could not conform to the strict parameters of the psychiatric CoCM but provide very similar services. They also stated that G0507 would be appropriate to report services furnished under other BHI models of care that may not require psychiatric services. We received a few comments describing particular models of care in great detail; a few commenters referenced the Veterans' Administration BHI care models, the Primary Care Behavioral Health/Behavioral Health Consultation (PCBH/BHC) Model, or general models in place within other health care systems. However, there was consensus among the commenters that another code(s) in addition to the psychiatric CoCM codes would be useful to collect information on how other behavioral health care models are being used and implemented.

Many commenters recommended that CMS provide more of a framework or description of included services and provider types without being unduly burdensome. Some commenters recommended service elements similar to the CCM service elements (continuity of care with a designated member of the care team; a written care plan; a comprehensive assessment of behavioral health or psychiatric and other medical conditions as well as any functional and psychosocial needs, updated as necessary; routine evaluation of patient progress using a tracking

system; services should be documented in the medical record and available to other treating professionals). These commenters recommended that eligible patients should have a diagnosed psychiatric or substance use disorder that requires care management services. Several commenters recommended that BHI payments be tied to the use of behavioral health assessment tools for screening and collection of treatment outcomes throughout the sessions of care in primary care. These commenters believed this would better position behavioral health to benefit from the movement toward value-based payment in the future. Some commenters assumed there is a designated behavioral health care manager for the service described by G0507, and recommended that we adopt similar rules for this care manager as apply for clinical staff providing CCM services.

Response: We continue to believe that another code, or set of BHI codes, in addition to the psychiatric CoCM code set would be useful to pay appropriately for BHI services furnished to Medicare beneficiaries. We also believe that such payment could facilitate our ability to identify and collect data regarding similar or related BHI service models. We agree with the commenters that we should provide more specificity around the services eligible for reporting under this other code(s). One way to do this would be to create codes with tiered times. Some commenters supported such an approach, while others believed it would be premature. At this time, we are not creating multiple levels of codes distinguishing levels of general BHI services using time or any other metric, but we may reconsider this in the future (also see section II.L on G0507 valuation).

Regarding included elements of the general BHI service (G0507), we agree with the commenters that we should be more specific in our definition of this service. We wish to provide greater specificity without being overly prescriptive, since a range of

activities may be included in BHI models of care other than the psychiatric CoCM. We believe we should include a core set of service elements that are similar to core elements of the psychiatric CoCM, especially a systematic process for initial assessment and routine follow up evaluation, revising the treatment approach or methods for patients who are not progressing or whose status changes; facilitating and coordinating behavioral health expertise and treatment; and designating a member of the care team with whom the beneficiary has a continuous relationship. We may revisit the included services in future years, but for CY 2017 the required service elements for the general BHI service (G0507) will be:

- Initial assessment or follow-up monitoring, including the use of applicable validated rating scales;
- Behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes;
- Facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation; and
- Continuity of care with a designated member of the care team.

Accordingly, the final code descriptor will be, G0507: Care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional, per calendar month, with the following required elements:

- Initial assessment or follow-up monitoring, including the use of applicable validated rating scales;
- Behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes;
- Facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation; and
- Continuity of care with a designated member of the care team.

We are aware of a number of validated rating scales that are available for use for a number of conditions addressed by BHI models of care, such as those described by the Kennedy Forum (see http://thekennedyforum-dot-org.s3.amazonaws.com/documents/MBC_supplement.pdf). We are requiring the use of such scales when applicable to the condition(s) that are being treated. Medication Assisted Treatment (MAT) may be a treatment that is facilitated under the facilitating treatment service element.

Regarding diagnosis, we believe we should specify similar diagnostic criteria for G0507 and the psychiatric CoCM services (G0502, G0503 and G0504). Accordingly we are providing that beneficiaries who are appropriate candidates for services billed under G0507 will have an identified psychiatric or behavioral health condition(s) that requires a behavioral health care assessment, behavioral health care planning, and provision of interventions. Eligible beneficiaries must present with a condition(s) that in the treating practitioner's clinical judgment, warrants the services included in G0507. The presenting condition(s) may be pre-existing or newly diagnosed by the treating practitioner, and may

be refined as treatment progresses. Beneficiaries receiving services reported under G0507 may, but are not required to have comorbid chronic or other medical condition(s) that are being managed by the treating practitioner. We are not limiting billing and payment for G0507 to a specified set of behavioral health conditions, because there may be overlap in behavioral health conditions; if we specified only certain diagnoses, practitioners might modify diagnoses to fit within payment rules; and for many beneficiaries for whom specialty care is not available, or who choose for other reasons to remain within primary care, their behavioral health condition(s) can be addressed using a model of integrated care.

Regarding rules for clinical staff, we are clarifying that services included in the code G0507 may be provided directly by the treating practitioner or provided by other qualifying individuals (whom we term “clinical staff”) under his or her direction, during the calendar month service period. Unlike the psychiatric CoCM codes, for G0507 there is not necessarily a specific individual designated as a “behavioral health care manager” with formal or specialized education in providing the services (although there could be). Similarly, there is not necessarily a psychiatric or other behavioral health specialist consultant (although there could be), and we note that G0507 is not valued to explicitly account for such a consultant. We will apply the same definition of the term “clinical staff” that we have applied for CCM to G0507, namely, the CPT definition of this term, subject to the incident to rules and regulations and applicable state law, licensure and scope of practice at 42 CFR 410.26. For G0507, then, we note that the term “clinical staff” will encompass or include a psychiatric or other behavioral health specialist consultant, if the treating practitioner obtains consultative expertise. Clinical staff that

provide included services do not have to be employed by the treating practitioner or located on site, necessarily, and may or may not be a professional who is permitted to independently furnish and report services to Medicare. Time spent by administrative or clerical staff cannot be counted towards the time required to bill G0507.

G0507 is valued to include minimal work by the treating practitioner; the bulk of the valuation is based on clinical staff time (see section II.L on valuation). However, we want to emphasize that the treating practitioner must direct the service, continue to oversee the beneficiary's care, and perform ongoing management, collaboration and reassessment. If the service (or part thereof) is provided incident to the treating practitioner's services, whether on site or remotely, the clinical staff providing services must have a collaborative, integrated relationship with the treating practitioner. They must also have a continuous relationship with the beneficiary.

Evaluation and management services, such as face-to-face E/M visits, may be separately billed during the service period or on the same day as G0507, provided time is not counted twice towards the same code.

For payment purposes, we are categorizing this service as a designated care management service assigned general supervision for purposes of "incident to" billing, because we do not believe it is clinically necessary for the individuals on the team who provide services other than the treating practitioner (namely, clinical staff) to have the treating practitioner immediately available to them at all times, as would be required under a higher level of supervision. However, general supervision sets the minimum standard for supervision and does not, by itself, meet the requirements we are setting for billing new code G0507. While certain aspects of G0507 might be furnished under

general supervision, we do not believe the general supervision requirement adequately describes the nature of the relationship and interactions of the respective team members for services furnished using BHI models of care or the codes we are creating to describe those services. Moreover the general supervision requirement only directly addresses the physical location of the treating practitioner, not the location of clinical staff, necessarily.

Comment: Regarding behavioral health care planning, some commenters noted that there is not necessarily value in accumulating or enumerating a number of different types of care plans addressing different aspects of the beneficiary's problems, such as a behavioral or psychiatric care plan, a CCM care plan, and a cognitive impairment care plan (see G0505 in section II.E.5).

Response: While any care planning should take into account the whole patient, our intent is that the care planning included in the CCM coding (and G0506, the CCM initiating visit add-on code) will be the most comprehensive in nature, addressing all health issues with particular focus on the multiple chronic conditions being managed by the treating practitioner. In contrast, the BHI care planning will focus on behavioral health or psychiatric issues, in particular, just as the cognitive impairment care planning will focus on cognitive impairment issues, in particular (see section II.E.5. of this final rule).

However, we understand that adoption of EHRs may be lower among behavioral health practitioners⁹ and note that resources are available to help inform how care plans can support team-based care and BHI.¹⁰ While we understand that practitioners, in

⁹ See for instance <http://dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php> and <https://www.thenationalcouncil.org/wp-content/uploads/2012/10/HIT-Survey-Full-Report.pdf>.

¹⁰ For instance, AHRQ has a variety of resources on how shared care plans can support team-based care and behavioral health integration at <https://integrationacademy.ahrq.gov/playbook/develop-shared-care-plan>

general, are exploring a wide variety of innovative approaches and tools that facilitate care plan integration across clinical disciplines, at this time, there may not be sufficient adoption of interoperable health IT interoperability among all practitioners and providers treating a given beneficiary to necessarily have a single, master care plan that adequately addresses the progress of the beneficiary in relation to all of these issues. In general, practitioners are encouraged to pursue approaches that integrate health information from multiple sources into a single care plan, but we understand that practitioners may need to create separate documents or the relevant care planning may be documented in another format within the medical record.

We believe the format of the care plan(s) is less important than having a process whereby feedback and expertise from all relevant practitioners and providers, whether internal or external to the billing practice, are integrated into the beneficiary's treatment plan and goals; that this plan be regularly assessed and revisited by the practitioner who is assuming an overall care management role for the beneficiary in a given month; that the patient is engaged in the care planning process; and that the care planning be documented in the medical record (as with any required element of any PFS service). We have framed the care planning service element for G0507 accordingly, "Behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes."

Comment: We received a few comments recommending codes in addition to the psychiatric CoCM codes that would pay for similar services to inpatients, or for behavioral health services by psychologists to psychologically and medically complex patients in skilled nursing facilities (SNF) and nursing homes. Some of these commenters stated that in SNF and

long-term care settings, psychologists work closely with primary care physicians, psychiatrists, nurses, and other consultants to improve outcomes by reducing inappropriate use or dosing of psychotropic medications, improving activities of daily living, and preventing avoidable admissions/falls. These commenters stated that many health systems employ psychologists as BHI team leaders or coordinators, and sought clarification on how psychologist-led teams would operationalize the new BHI codes. These commenters believe that psychology training provides unique skills in facilitating interdisciplinary teams. While they acknowledged that psychologists are not qualified to perform the full range of BHI services and interventions, they believed psychologists should be able to separately report and bill for care coordination and BHI initiation activities.

We received similar comments supporting the addition of psychiatric collaborative care services to the PFS, and other evidence-based models in a variety of primary care-based treatment settings. However, these commenters supported the inclusion of social workers at all levels of licensures as reimbursable providers of these services.

Response: We appreciate the commenters' descriptions of some particular working models of care, and we welcome additional information in this regard. We continue to believe it would be appropriate to have new coding for a range of BHI care models applicable to inpatient as well as outpatient and facility settings. Our goal in separately identifying and paying for BHI services is to prioritize accurate payment for these services, in recognition of the associated time and complexity of the services. We agree that beneficiaries who are admitted to a facility, are in long-term care, or are transitioning among settings during the month are likely to be more complex than other types of patients, and to warrant more- not less- BHI services. Therefore, we have valued

G0507 in both facility and non-facility settings (see section II.L on valuation). We are not limiting the time that can be counted towards the monthly time requirement to bill G0507 to time that is spent in the care of an outpatient or a beneficiary residing in the community. As we provide for the psychiatric CoCM services, G0507 may be reported by specialties that are not “traditional” primary care specialties, if such specialists furnish the included services. However, we stress that G0507 can only be reported by a treating physician or other qualified health care professional when he or she has directed the BHI service for the duration of time that he or she is reporting it, and has a qualifying relationship with individuals providing the service under his or her direction and control. Also, time and effort that is spent managing care transitions for CCM or TCM patients and that is counted towards reporting TCM or CCM services, cannot also be counted towards reporting any transitional care management activities reported under a BHI service code(s). We welcome additional input from stakeholders regarding appropriate (or inappropriate) settings of service for G0507.

Since the BHI initiating visit that is required to bill G0507 is not within the scope of practice of a psychologist or social worker (see below), psychologists and social workers will not be able to report G0507 directly (although a psychiatrist may be able to do so). Psychologists and social workers may provide care management services included in G0507 incident to the services of another (billing) practitioner. They may also provide services that are separately billable during the service period. We appreciate the commenters’ support for team-based care, and we recognize the substantial role of various types of mental health professionals within a primary care team. We are interested in receiving additional input from stakeholders as to whether and why

behavioral health care management services by a social worker, psychologist or similarly qualified professional should be reportable in its own right, rather than incident to the services of a practitioner authorized to bill Medicare for a BHI initiating visit. Consistent with our recent approaches to making proposals under PFS notice and comment rulemaking, we could consider adopting new coding under a different construct that was not defined as BHI, if stakeholders provided sufficient input on how to design, define and value the services. We would also consider such changes if adopted by the CPT Editorial Panel, per our usual process. BHI integrates behavioral health expertise into evaluation and management care. Therefore G0507 is designed to include services that require the oversight and involvement of a practitioner who can perform evaluation and management services, including facilitation of any needed pharmacotherapy, referral for specialty care, and overall management of the beneficiary's treatment in relation to primary care treatment. We note that G0507 would not be independently billed by psychologists or social workers, though from our understanding of various models of BHI, these professionals seem likely to be participants in team-based care for beneficiaries receiving these services.

c. BHI Initiating Visit

Similar to CCM services (see section II.E.4), we proposed to require an initiating visit for all of the BHI codes (G0502, G0503, G0504 and G0507) that would be billable separate from the BHI services themselves. We proposed that the same services that can serve as the initiating visit for CCM services (see section II.E.4.a. of this final rule) could serve as the initiating visit for the proposed BHI codes. The initiating visit would establish the beneficiary's relationship with the billing practitioner (most aspects of the BHI services would be furnished incident to the

billing practitioner's professional services), ensure the billing practitioner assesses the beneficiary prior to initiating care management processes, and provide an opportunity to obtain beneficiary consent (discussed below). We solicited public comment on the types of services that are appropriate for an initiating visit for the BHI codes, and within what timeframe the initiating visit should be conducted prior to furnishing BHI services.

Comment: The commenters were largely supportive of our proposal to allow the same services to qualify for the initiating visit to CCM as for the initiating visit to BHI services. We received a few comments stating that in addition to the qualifying E/M services (or an AWW or IPPE), initiating services should include in-depth psychological evaluations delivered by a psychologist including CPT codes 90791, 96116 or 96118 which, in turn, include care plan development. These commenters agreed that psychologists cannot personally furnish all BHI services (for example, medication reconciliation), but believe psychologists effectively coordinate care and perform other aspects of BHI services as part of a team under current practice models. They believe this approach would be particularly effective for reducing inappropriate use or dosing of psychotropic medications in elderly and complex patients, improving activities of daily living, and preventing avoidable admissions and falls.

Response: We appreciate the commenters' feedback. We agree that psychologists would be qualified to perform care coordination that is included in the psychiatric CoCM codes (G0502, G0503 and G0504) and the general BHI code (G0507) under the direction of a physician or other qualified health care professional. In addition, beneficiaries receiving BHI services under any of those codes may be referred to psychologists for psychotherapy or other services that are separately billable and within the scope of practice of psychologists, as discussed elsewhere in this section of our final rule. However many commenters acknowledged,

and we agree, that a BHI initiating visit is necessary. The initiating visit is not, in its entirety, within the scope of psychologist practice. Therefore, we are finalizing our proposal that the same services that qualify as the initiating visit for CCM will also qualify as initiating services for BHI, and they do not include in-depth psychological evaluation by a psychologist. Also, we will require an initiating visit for BHI only for new patients or beneficiaries not seen within a year of commencement of BHI services (the same requirement we are finalizing for CCM, see section II.E.4.a). As more experience is gained with the psychiatric CoCM services and other models of BHI care, we may reassess these provisions.

As discussed above, we are interested in receiving input from stakeholders regarding circumstances other than BHI in which behavioral health care management services by a psychologist, social worker or similarly qualified professional should be reportable in its own right, rather than incident to the services of a practitioner authorized to bill Medicare for a BHI initiating visit.

Comment: Some commenters recommended that CMS establish an add-on code to the initiating visit for BHI services, parallel to G0506 (the proposed add-on code for the CCM initiating visit).

Response: We do not believe we have enough information about practice patterns at this time to create an add-on code to the BHI initiating visit, and we did not propose such a code. We may re-examine this issue in the future.

d. Beneficiary Consent for BHI Services

Commenters to the CY 2016 PFS proposed rule indicated that they did not believe a specific patient consent for BHI services is necessary and indicated that requiring special informed consent for these services may reduce access due to stigma associated with behavioral

health conditions. Instead, the commenters recommended requiring a more general consent prior to initiating these services whereby the beneficiary gives the initiating physician or practitioner permission to consult with relevant specialists, which would include conferring with a psychiatric consultant. Accordingly, we proposed to require a general beneficiary consent to consult with relevant specialists prior to initiating these services, recognizing that applicable rules continue to apply regarding privacy. The proposed general consent would encompass conferring with a psychiatric consultant when furnishing the psychiatric CoCM codes (G0502, G0503, and G0504) or the proposed broader BHI code (G0507). Similar to the proposed beneficiary consent process for CCM services, we proposed that the billing practitioner must document in the beneficiary's medical record that the beneficiary's consent was obtained to consult with relevant specialists including a psychiatric consultant, and that, as part of the consent, the beneficiary is informed that there is beneficiary cost-sharing, including potential deductible and coinsurance amounts, for both in-person and non-face-to-face services that are provided. We solicited stakeholder comments on this proposal.

We recognized that special informed consent could also be helpful in cases when a particular service is limited to being billed by a single practitioner for a particular beneficiary. We did not believe that there are circumstances where it would be reasonable for multiple practitioners to be reporting these codes during the same month. However, we did not propose a formal limit at this time. We solicited comment on whether such a limitation would be beneficial or whether there are circumstances under which a beneficiary might reasonably receive BHI services from more than one practitioner during a given month.

Comment: The commenters were largely supportive of our proposal regarding BHI consent, some noting that physician-to-physician communication as well as communication

within treatment teams happens routinely, without an extra layer of formal written consent, for other medical conditions. A few commenters intimated that CMS might pursue a single broad consent that could be used across care management services; for example, applying for both CCM and BHI. We did not receive any public comments delineating the circumstances under which it would be appropriate to bill for services furnished using more than one BHI service model per month, or appropriate for more than one practitioner (whether in the same practice or different practices) to bill for services furnished in a BHI care model per month.

Response: We agree with the commenters that physician-to-physician communication as well as communication within treatment teams happens routinely, without an extra layer of formal written consent, for other medical conditions. However there are particular privacy concerns addressed by other rules and regulations for some behavioral health or substance use care. Also we are concerned that beneficiaries should not incur unexpected expenses for care that is largely, or in significant part, non-face-to-face in nature. Finally, there are issues to consider, that we considered for CCM, regarding prevention of duplicative practitioner billing, and whether BHI services can actually be furnished under the direction and control of any given practitioner if for a given service period, more than one practitioner is furnishing BHI services and billing them.

The public comments were supportive of our proposal for a broad consent that could be verbally obtained but must be documented in the medical record, and we are finalizing as proposed. At this time, we do not believe a single consent process for both BHI and CCM is advisable. It is not clear how frequently BHI and CCM would or should be furnished concurrently. BHI and CCM are distinct, separate services, having significant differences in time thresholds, the nature of the services, types of individuals providing the services, and

payment and cost sharing amounts. Therefore, at this time, we are maintaining separate consent processes for CCM and BHI, as provided in the respective sections of this final rule. Also, as discussed in section II.E.4 on CCM, CCM and BHI may be billed during the same service period.

It remains unclear whether it would be reasonable and necessary for more than one practitioner (whether in the same practice or different practices) to bill BHI services for a given beneficiary for a given service period, given the lack of public response and input on this issue. It may depend on the conditions(s) being treated and whether specialty care, other than psychiatric or behavioral health specialty care, and primary care are both involved. We are not proposing a formal limit at this time, but we stress that BHI services can only be reported by a treating physician or other qualified health care professional when he or she has obtained the required beneficiary consent, directed the BHI services he or she reports for the duration of time reported, and has a qualifying relationship with individuals providing the reported services under his or her direction and control. We would not expect a single practitioner to furnish care to a given beneficiary under more than one BHI model of care during a given month. Therefore 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 for a given beneficiary. We remind stakeholders that time cannot be counted more than once towards any code(s), all services must be medically reasonable and necessary, and that beneficiary cost sharing and advance consent apply. We will be monitoring the claims data and studying the utilization patterns. We will continue to assess appropriate reporting patterns, and we expect that potential coding changes by the CPT Editorial Panel may inform this issue.

Comment: We received a number of comments recommending that cost sharing be removed for all care management services, whether through legislative change, demonstration, waiver safe harbor, or designation as preventive services.

Response: We appreciate commenters' concerns and recognize many of the challenges associated with patient cost-sharing for these kinds of services. At this time, we do not have authority to waive cost sharing for the BHI or other care management services. We appreciate the commenters' acknowledgement of our current limitations and we will continue to consider this issue.

e. Summary of Final BHI Policies

Beginning in CY 2017, we are providing separate payment for a range of BHI services. Specifically, we are providing payment for psychiatric CoCM services under the following codes:

- G0502: Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements:

- ++ Outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional;

- ++ Initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan;

- ++ Review by the psychiatric consultant with modifications of the plan if recommended;

++ Entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant; and

++ Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.

● G0503: Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements:

++ Tracking patient follow-up and progress using the registry, with appropriate documentation;

++ Participation in weekly caseload consultation with the psychiatric consultant;

++ Ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers;

++ Additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant;

++ Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies;

++ Monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment.

- G0504: Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional (List separately in addition to code for primary procedure) (Use G0504 in conjunction with G0502, G0503).

These psychiatric CoCM services are reported by the treating physician or other qualified health care professional for services furnished during a calendar month service period. These services may be furnished when a beneficiary has a psychiatric or behavioral health condition(s) that in the treating physician or other qualified health care professional's clinical judgment, requires a behavioral health care assessment; establishing, implementing, revising, or monitoring a care plan; and provision of brief interventions. The diagnosis or diagnoses may be pre-existing or made by the treating physician or other qualified health care professional, and may be refined over time. The psychiatric CoCM services may be furnished to beneficiaries with any psychiatric or behavioral health condition(s) that is being treated by the physician or other qualified health care professional, including substance use disorders. Beneficiaries receiving psychiatric CoCM services may, but are not required to have comorbid chronic or other medical condition(s) that are being managed by the treating practitioner.

Psychiatric CoCM services include the services of the treating physician or other qualified health care professional, the behavioral health care manager (see description below) who provides services incident to services of the treating physician or other qualified health care professional, and the psychiatric consultant (see description below) whose consultative services are furnished incident to services of the treating physician or other qualified health care

professional. Time spent by administrative or clerical staff cannot be counted towards the time required to bill the psychiatric CoCM service codes.

Beneficiaries receiving psychiatric CoCM services may have newly diagnosed conditions, need help in engaging in treatment, have not responded to standard care delivered in a non-psychiatric setting, or require further assessment and engagement prior to consideration of referral to a psychiatric care setting. Beneficiaries are treated for an episode of care, defined as beginning when the behavioral health care manager engages in care of the beneficiary under the appropriate supervision of the billing practitioner and ending with:

- The attainment of targeted treatment goals, which typically results in the discontinuation of care management services and continuation of usual follow-up with the treating physician or other qualified healthcare professional; or
- Failure to attain targeted treatment goals culminating in referral to a psychiatric care provider for ongoing treatment; or
- Lack of continued engagement with no psychiatric collaborative care management services provided over a consecutive 6-month calendar period (break in episode).

A new episode of care will start after a break in episode of 6 calendar months or more.

The treating physician or other qualified health care professional directs the behavioral health care manager and continues to oversee the beneficiary's care, including prescribing medications, providing treatments for medical conditions, and making referrals to specialty care when needed. The treating physician or other qualified health care professional must remain involved in ongoing oversight, management, collaboration and reassessment as appropriate to bill the psychiatric CoCM codes.

The behavioral health care manager has formal education or specialized training in behavioral health (which could include a range of disciplines, for example, social work, nursing, and psychology). The behavioral health care manager provides care management services, as well as an assessment of needs, including the administration of validated rating scales¹¹; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; provision of brief interventions; ongoing collaboration with the treating physician or other qualified health care professional; maintenance of a registry¹²; all in consultation with the psychiatric consultant. The behavioral health care manager is available to provide these services face-to-face and non-face-to-face, and consults with the psychiatric consultant minimally on a weekly basis.

The behavioral health care manager must have a collaborative, integrated relationship with the rest of the care team members, and be able to perform all of the required elements of the service delineated for the behavioral health care manager. The behavioral health care manager must have the ability to engage the beneficiary outside of regular clinic hours as necessary to perform the behavioral health care manager's duties under the psychiatric CoCM model, and must have a continuous relationship with the beneficiary. The behavioral health care manager may or may not be a professional who meets all the requirements to independently furnish and report services to Medicare. The behavioral health care manager is subject to the incident to rules and regulations and applicable state law, licensure and scope of practice (see 42 CFR 410.26).

The psychiatric consultant is a medical professional trained in psychiatry and qualified to prescribe the full range of medications. The psychiatric consultant advises and makes

¹¹ For example, see <https://aims.uw.edu/resource-library/measurement-based-treatment-target>.

¹² For example, see <https://aims.uw.edu/collaborative-care/implementation-guide/plan-clinical-practice-change/identify-population-based>.

recommendations, as needed, for psychiatric and other medical care, including psychiatric and other medical diagnoses, treatment strategies including appropriate therapies, medication management, medical management of complications associated with treatment of psychiatric disorders, and referral for specialty services, that are communicated to the treating physician or other qualified health care professional, typically through the behavioral health care manager. The psychiatric consultant does not typically see the beneficiary or prescribe medications, except in rare circumstances, but can and should facilitate referral for direct provision of psychiatric care when clinically indicated. The psychiatric consultant is subject to the incident to rules and regulations and applicable state law, licensure and scope of practice (see 42 CFR 410.26).

Beginning in CY 2017, we are providing separate payment for BHI services furnished under models of care other than the psychiatric CoCM model, under HCPCS code G0507: Care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional, per calendar month, with the following required elements:

- Initial assessment or follow-up monitoring, including the use of applicable validated rating scales;
- Behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes;
- Facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation; and
- Continuity of care with a designated member of the care team.

G0507 is reported by the treating physician or other qualified health care professional for services furnished during a calendar month service period. This service may be furnished when the beneficiary has a psychiatric or behavioral health condition(s) that in the treating physician or other qualified health care professional's clinical judgment, requires a behavioral health care assessment, behavioral health care planning, and provision of interventions. The presenting condition(s) may be pre-existing or newly diagnosed by the treating physician or other qualified health care professional, and may be refined over time. Beneficiaries receiving services reported under G0507 may have any psychiatric or behavioral health condition(s) that is being treated by the physician or other qualified health care professional, including substance use disorders. Beneficiaries receiving services reported under G0507 may, but are not required to have comorbid chronic or other medical condition(s) that are being managed by the treating practitioner.

Services reported under G0507 may be provided directly by the treating physician or other qualified health care professional, or provided by clinical staff under his or her direction, during a calendar month service period. For G0507, there is not necessarily a specific individual designated as a "behavioral health care manager" with formal or specialized education in providing the services (although there could be). Similarly, there is not necessarily a psychiatric or other behavioral health specialist consultant (although there could be) and we note that G0507 is not valued to explicitly account for expert consultation. For G0507, the term "clinical staff" means the CPT definition of this term, subject to the incident to rules and regulations and applicable state law, licensure and scope of practice at 42 CFR 410.26. For G0507, then, we note that the term "clinical staff" will encompass or include any psychiatric or other behavioral health specialist

consultant that may provide consultative services. Clinical staff providing services are not required to be employed by the treating practitioner or located on site, and these individuals may or may not be a professional permitted to independently furnish and report services to Medicare. Time spent by administrative or clerical staff cannot be counted towards the time required to report G0507. We emphasize that the physician or other qualified health care professional must direct the service, continue to oversee the beneficiary's care, and perform ongoing management, collaboration and reassessment. If the service (or part thereof) is provided incident to services of the treating practitioner, whether on site or remotely, the clinical staff providing services must have a collaborative, integrated relationship with the treating practitioner. They must also have a continuous relationship with the beneficiary.

For all of the BHI service codes (G0502, G0503, G0504 and G0507), we are requiring an initiating visit that is billable separate from the BHI services themselves. The same services that qualify as initiating visits for CCM services can serve as the initiating visit for BHI services (certain face-to-face E/M services including the face-to-face visit required for TCM services, and the AWW or IPPE). The BHI initiating visit establishes the beneficiary's relationship with the treating practitioner (BHI services may be furnished incident to the treating practitioner's professional services); ensures that the treating practitioner assesses the beneficiary prior to initiating care management processes; and provides an opportunity to obtain beneficiary consent (consent may also be obtained outside of the BHI initiating visit, as long as it is obtained prior to commencement of BHI services).

For all of the BHI service codes, we are also requiring prior beneficiary consent, recognizing that applicable rules continue to apply regarding privacy. The consent will include

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, AWW 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, AWW, 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 AWWs) 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 AWWs).

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 AWWs 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

<p>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.</p>
<p>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.</p>
<p>24/7 Access & Continuity of Care</p> <ul style="list-style-type: none"> • 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.
<p>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.</p>
<p>Comprehensive Care Plan</p> <ul style="list-style-type: none"> • 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.
<p>Management of Care Transitions</p> <ul style="list-style-type: none"> • 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.
<p>Home- and Community-Based Care Coordination</p> <ul style="list-style-type: none"> • 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.
<p>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.</p>
<p>Beneficiary Consent</p> <ul style="list-style-type: none"> • 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.
<p>Medical Decision-Making- Complex CCM services require and include medical decision-making of moderate to high complexity (by the physician or other billing practitioner).</p>

5. Assessment and Care Planning for Patients with Cognitive Impairment (GPPP6)

For CY 2017 we proposed a G-code that would provide separate payment to recognize the work of a physician (or other appropriate billing practitioner) in assessing and creating a care plan for beneficiaries with cognitive impairment, such as from Alzheimer's disease or dementia, at any stage of impairment, G0505 (Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history obtained from patient and/or caregiver, in office or other outpatient setting or home or domiciliary or rest home). We understand that a similar code was recently approved by the CPT Editorial Panel and is scheduled to be included in the CY 2018 CPT code set. We intended for G0505 to be a temporary code, perhaps for only one year, to be replaced by the CPT code in CT 2018. We will consider whether to adopt and establish relative value units for the new CPT code under our standard process, presumably for CY 2018.

We reviewed the list of service elements that were considered by the CPT Editorial Panel, and proposed the following as required service elements of G0505:

- Cognition-focused evaluation including a pertinent history and examination.
- Medical decision making of moderate or high complexity (defined by the E/M guidelines).
- Functional assessment (for example, Basic and Instrumental Activities of Daily Living), including decision-making capacity.
- Use of standardized instruments to stage dementia.
- Medication reconciliation and review for high-risk medications, if applicable.
- Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized instrument(s).

- Evaluation of safety (for example, home), including motor vehicle operation, if applicable.
- Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks.
- Advance care planning and addressing palliative care needs, if applicable and consistent with beneficiary preference.
- Creation of a care plan, including initial plans to address any neuropsychiatric symptoms and referral to community resources as needed (for example, adult day programs, support groups); care plan shared with the patient and/or caregiver with initial education and support

The proposed valuation of G0505 (discussed in section II.E.1) assumed that this code would include services that are personally performed by the physician (or other appropriate billing practitioner, such as a nurse practitioner or physician assistant) and would significantly overlap with services described by certain E/M visit codes, advance care planning services, and certain psychological or psychiatric service codes that are currently separately payable under the PFS. Accordingly, we proposed that G0505 must be furnished by the physician (or other appropriate billing practitioner) and could not be billed on the same date of service as CPT codes 90785 (Psytx complex interactive), 90791 (Psych diagnostic evaluation), 90792 (Psych diag eval w/med srvcs), 96103 (Psycho testing admin by comp), 96120 (Neuropsych tst admin w/comp), 96127 (Brief emotional/behav assmt), 99201-99215 (Office/outpatient visits new), 99324-99337 (Domicil/r-home visits new pat), 99341-99350 (Home visits new patient), 99366-99368 (Team conf w/pat by hc prof), 99497 (Advncd care plan 30 min), 99498 (Advncd care plan addl 30 min)), since these codes all reflect face-to-face services furnished by the physician or other

billing practitioner for related separately billable services that overlap substantially with G0505. In addition, we proposed to prohibit billing of G0505 with other care planning services, such as care plan oversight services (CPT code 99374), home health care and hospice supervision (G0181, G0182), or our proposed add-on code for comprehensive assessment and care planning by the billing practitioner for patients requiring CCM services (GPPP7). We solicited comment on whether there are circumstances where multiple care planning codes could be furnished without significant overlap. We proposed to specify that G0505 may serve as a companion or primary E/M code to the prolonged service codes (those that are currently separately paid, and those we proposed to separately pay beginning in 2017), but were interested in public input on whether there is any overlap among these services. We solicited comment on how to best delineate the post-service work for G0505 from the work necessary to provide the prolonged services code.

We did not believe the services described by G0505 would significantly overlap with proposed or current medically necessary CCM services (CPT codes 99487, 99489, 99490); TCM services (CPT codes 99495, 99496); or the proposed behavioral health integration service codes (HCPCS codes GPPP1, GPPP2, GPPP3, GPPPX). Therefore, we proposed that G0505 could be billed on the same date-of-service or within the same service period as these codes (CPT codes 99487, 99489, 99490, 99495, 99496, and HCPCS codes GPPP1, GPPP2, GPPP3, and GPPPX). There may be overlap in the patient population eligible to receive these services and the population eligible to receive the services described by G0505, but we believed there would be sufficient differences in the nature and extent of the assessments, interventions and care planning, as well as the qualifications of individuals providing the services, to allow concurrent billing for services that are medically reasonable and necessary. We solicited public comment

on potential overlap between G0505 and other codes currently paid under the PFS, as well as the other primary care/cognitive services addressed in this section of the final rule.

Comment: Many commenters were supportive of the proposal, including the provisions regarding scope of service elements, conditions of payment, and overlap with other services under the PFS.

Response: We thank commenters for their support of the proposed scope of service, conditions of payment, and overlap with other services under the PFS for G0505. We believe that by improving payment accuracy by paying separately for this service, practitioners will be able to accurately assess patients for cognitive impairment, particularly in early stages.

Comment: We received numerous comments stating that assessment and staging for dementia is very sensitive and should only be conducted by neuropsychologists, who would be unable to bill G0505. Commenters were concerned that untrained professionals conducting assessments for dementia would lead to errors in diagnosis and inappropriate treatment. Commenters encouraged CMS to not finalize this code and maintain the current coding for psychological and neuropsychological assessment or suggested that CMS remove the bullet points associated with medication management or medical decision making so that G0505 could be billed by psychologists.

Response: While we acknowledge and support the work of psychologists and neuropsychologists in the care of Medicare beneficiaries, we continue to believe that this code describes a distinct PFS service that may be reasonable and necessary in the diagnosis and treatment of a beneficiary's illness. We remind interested stakeholders that we routinely examine the valuation and coding for existing services under the potentially misvalued code initiative, and that there is a the process for public nomination of particular codes. If

stakeholders have information to suggest that the current coding for neuropsychological and psychological testing is inaccurate, we welcome nominations under the established process.

Comment: A few commenters encouraged CMS to avoid adopting scope of service elements that are exhaustive as these may create barriers to utilization, while other commenters made the following recommendations regarding the scope of service provisions:

- Expand scope of service elements related to medication management.
- Include occupational therapy in the scope of service element pertaining to community resources.
- Rewrite “Creation of a care plan, including initial plans to address any neuropsychiatric symptoms and referral to community resources as needed (for example, adult day programs, support groups); care plan shared with the patient and/or caregiver with initial education and support” to include “identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness and availability of caregiver to voluntarily take on caregiving tasks.”
- Make sure that non-paid or informal caregivers are included in care planning and provide resources and support for care givers so as to improve care givers ability to provide care for the beneficiary.
- Require the inclusion of caregiver names in care plan and patients medical record, require that caregivers be assessed for stress and depressive symptoms, as well as care giver skill and education needs.
- State that consultations with the caregiver are permissible under HIPAA and that such conversations may be necessary in the development of a care plan.

- Specify that any advance care planning is consistent with beneficiary preference and addresses any palliative care needs of the patient, and include establishment of durable power of attorney.
- Clarify that diagnosis of dementia is not part of the scope of service by deleting “cognition focused evaluation including pertinent history” from the scope of service.
- Clarify that “functional assessment” is separate from decision making assessments, and that this is a non-legal assessment of competency.
- Stipulate that other decision makers should be identified.
- Consider deleting “use of standardized instruments to stage dementia” because the care plan is the most important aspect of the service and many standardized instruments are not very effective at staging.
- Clarify that the care plan address both medical and non-medical issues, and includes follow-up scheduling for monitoring and evaluation.
- Provide a copy of the written care plan to the patient.
- Refer to the care plan as a “person-centered care plan.”
- Include evaluation of medical problems including review of lab or imaging tests, review of co-morbidities, especially those which are dependent on self-care, evaluation the risk of falls and recommendations for fall prevention, evaluation of possible elder abuse, and documentation of financial issues, as part of the scope of service.

Response: We appreciate the information provided by commenters on the best practices associated with furnishing this service and would encourage stakeholders to adopt any or all of these scope of service provisions, such as the inclusion of caregivers in care planning. The scope of service for assessment and care planning service for patients with cognitive impairment does

not prohibit stakeholders from adopting any additional scope of service provisions which may be beneficial for the treatment of the patient. However, we do not believe that the ability to fully furnish this service and establish an appropriate value for it is contingent on meeting such conditions. Therefore, we do not believe they should be added to the scope of service. We concur with commenters on the necessity of avoiding the imposition of overly burdensome restrictions within the scope of service.

Comment: Some commenters requested that CMS clarify that not all elements in the scope of service need to be provided by the billing practitioner and many can be provided by others incident to the billing practitioner's services. One commenter stated that there are circumstances where the best practitioner to provide a specific service element does not work in the same practice as the billing practitioner, and therefore the billing practitioner should be able to contract out for provision of some aspects, provided that the billing practitioner remain in oversight. Other commenters stated that CMS should make G0505 billable by other practitioners, such as occupational therapists, or community based entities.

Response: G0505 is a service that includes central elements, which must be performed by the billing practitioner subject to established E/M guidelines. Only those practitioners eligible to report E/M services should report this service. Outside of the specified elements, the regular incident-to rules apply consistent with other E/M services. We believe that physicians and eligible non-physician practitioners, such as a nurse practitioners and physician assistants should exclusively bill for this code.

Comment: Many commenters suggested that CMS expand HCPCS code G0505 or pay separately for similar services furnished to patients with other advanced or life threatening illnesses.

Response: We appreciate the comments on other conditions that could benefit from assessment and care planning and will consider these for future rulemaking. We are finalizing the G0505 code to pay separately for the assessment and care plan creation for beneficiaries with cognitive impairment, such as from Alzheimer's disease or dementia, at any stage of impairment.

Comment: Commenters provided many examples of how CMS could develop appropriate quality and outreach measures to ensure appropriate utilization of G0505. Commenters encouraged CMS to closely monitor use of G0505 for a few years following implementation, so as to ascertain whether patient eligibility is an issue in uptake for the code.

Response: We appreciate the information on quality and outreach measures. CMS is engaged in the use of measures to improve quality and access to care. CMS intends to monitor utilization and will consider how conditions of payment align with best practices and quality measures.

Comment: One commenter urged CMS to make the proposed coding and payment changes available to physicians in total cost of care models, such as ACOs and bundled payment programs.

Response: Our proposal relates only to payment for services under the Medicare PFS. We note that the codes and payment amounts that we finalize for services will be available for billing and payment under the PFS for CY 2017. In general, we do not address in this final rule, and instead defer to the policies regarding billing and payment for these services that are applicable within individual Center for Medicare & Medicaid Innovation models and other programs. However, as our policies regarding payment for new primary care codes are applicable beginning in CY 2017, we note that models may need to update their policies to prevent potential duplication of payment between the PFS and the models. For example, where

CCM services have been excluded from separate payment under existing models, newly established care management services (including complex CCM, psychiatric CoCM, and BHI) may likewise be excluded.

Comment: One commenter stated that many small practices do not have the infrastructure to support a multi-disciplinary team of practitioners and urged CMS to allow flexibility for solo and small group practices to share resources. The commenter also suggested that CMS offer a one-time incentive for practices to integrate service elements into workflow.

Response: In general, the coding under the PFS is intended to describe services as they are furnished and are valued using typical resource costs. We appreciate the concern of commenters regarding access, and we are eager to hear from stakeholders regarding concerns related to access for these and other PFS services.

6. Improving Payment Accuracy for Care of People with Disabilities (GDDD1)

We estimate that about 7 percent of all Medicare beneficiaries have a potentially disabling mobility-related diagnosis (the Medicare-only prevalence is 5.5 percent and the prevalence for Medicare-Medicaid dual eligible beneficiaries is 11 percent), using 2010 Medicare (and for dual eligible beneficiaries, Medicaid) claims data.

When a beneficiary with a mobility-related disability goes to a physician or other practitioner's office for an E/M visit, the resources associated with providing the visit can exceed the resources required for the typical E/M visit. An E/M visit for a patient with a mobility-related disability can require more physician and clinical staff time to provide appropriate care because the patient may require skilled assistance throughout the visit to carefully move and adjust his/her body. Furthermore, an E/M visit for a patient with a mobility-related disability commonly requires specialized equipment such as a wheel chair accessible scale, floor and overhead lifts, a

movable exam table, padded leg supports, a stretcher and transfer board. The current E/M visit payment rates, based on an assumption of “typical” resources involved in furnishing an E/M visit to a “typical” patient, do not accurately reflect these additional resources associated with furnishing appropriate care to many beneficiaries with mobility-related disabilities.

When furnishing E/M services to beneficiaries with mobility-related disabilities, practitioners face difficult choices in deciding whether to take the extra time necessary and invest in the required specialized equipment for these visits even though the payment rate for the service does not account for either expense; potentially providing less than optimal care for a beneficiary whose needs exceed the standard appointment block of time in the standard equipped exam room reflected in the current E/M visit payment rate; or declining to accept appointments altogether for beneficiaries who require additional time and specialized equipment.

Each of these scenarios is potentially problematic. The first two scenarios suggest that the quality of care for this beneficiary population might be compromised by assumptions under the PFS regarding relative resource costs in furnishing services to this population. The third scenario reflects an obvious access problem for these beneficiaries. To improve payment accuracy and help ameliorate potential disparity in access and quality for beneficiaries with mobility-related disabilities, we proposed to create a new add-on G-code, effective for CY 2017, to describe the additional services furnished in conjunction with E/M services to beneficiaries with disabilities that impair their mobility:

G0501: Resource-intensive services for patients for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lifts, and adjustable padded leg supports) is medically necessary and used during the provision of

an office/outpatient evaluation and management service visit (Add-on code, list separately in addition to primary procedure).

Effective January 1, 2017, we proposed that this add-on code could be billed with new and established patient office/outpatient E/M codes (CPT codes 99201 through 99205, and 99212 through 99215), as well as transitional care management codes (CPT codes 99495 and 99496), when the additional resources described by the code are medically necessary and used in the provision of care. In addition to seeking comment on this proposal, we are also sought comment on other HCPCS codes that may be appropriate base codes for this proposed add-on code, including those describing preventive visits and services. We reminded potential commenters that the rationale for this proposal is based in large part on the broad use and lack of granularity in coding for E/M services relative to other PFS services in conjunction with the additional resources used.

We received many thoughtful comments on this proposal and thank commenters for their input. Comments received are summarized below.

Comment: Most commenters agreed with the proposed rule's statement of disability disparities and discussed a variety challenges that individuals with disabilities face in accessing the health care system. Several of these commenters cited evidence of existing challenges for individuals with mobility-related disabilities, including a lack of physically accessible equipment within physician offices, barriers to communication, and a lack of existing tools to recognize, track, and consistently meet specialized needs. Commenters applauded CMS for offering a concrete proposal with significant funding to meaningfully address this problem and noted that 26 years after passage of the Americans with Disabilities Act, it is alarming that physical and communication barriers in physicians' and other health care professionals' offices still exist

across the country. However, some commenters suggested that the root cause and scope of these issues are not well characterized, and suggested that CMS work with stakeholders to conduct additional studies and gain information as to the underlying reasons for barriers to access to care and lower quality scores on certain measures.

Generally, commenters noted that they appreciate CMS' efforts to address health disparities based on disability, and some then supported this proposal as a first step in providing medically necessary services to patients with disabilities, while others recommended that CMS not finalize the proposal and raised legal, access, and equity concerns.

Response: We agree with commenters that individuals with disabilities face additional barriers to access health care, an issue that contributes to widespread disparities in outcomes. We also agree with commenters that the underlying reasons for these disparities are multifaceted and can include payment challenges, physical accessibility and communication barriers, a lack of awareness among health care providers in assessing and fully addressing the needs and preferences of people with disabilities, and others issues. As a result of all these factors, individuals with disabilities can face challenges in scheduling appointments, and in finding and maintaining a primary care provider, an essential foundation for accessing the health system.

Although there was near universal agreement among commenters regarding problems in health care disparities and barriers to access among individuals with disabilities, there was disagreement about whether establishing payment for code G0501 as proposed was a good solution to help solve these problems. While we believe that improving the payment accuracy of physicians' services is necessary and appropriate, and can help to address the underlying access issues for individuals with disabilities, we also acknowledge that implementation of new or revised payments can result in unanticipated, and potentially undesirable, consequences. Before

implementing payment for code G0501, we plan to further analyze and address the concerns raised by commenters. As such, we are not finalizing payment for code G0501 at this time. We appreciate commenters' insights, and our commitment to promoting better primary care for people with disabilities remains strong. Over the next 6 months we will engage with interested beneficiaries, advocates, and practitioners to continue to explore improvements in payment accuracy for care of people with disabilities. We intend to discuss this issue again in future rulemaking.

While we are not finalizing separate payment for code G0501 for CY 2017, we are including the code in the CY 2017 code set as G0501. The HCPCS code G0501 will not be payable under the Medicare PFS for CY 2017, though practitioners will be able to report the code, should they be inclined to do so.

a. Soliciting Comment on Other Coding Changes to Improve Payment Accuracy for Care of People with Disabilities

When furnishing care to a beneficiary with a mobility-related disability, the current E/M visit payment rates may not fully reflect the associated resource costs that are being incurred by practitioners. We recognize that there are other populations for which payment adjustment may be appropriate. Our proposal regarding beneficiaries with mobility-related disabilities reflected the discrete nature of the additional resource costs for this population, the clear lack of differentiation in resource costs regarding particular kinds of frequently-furnished services, and the broad recognition of access problems. We recognize that some physician practices may frequently furnish services to particular populations for which the relative resource costs are similarly systemically undervalued and we sought comment regarding other circumstances where these dynamics can be discretely observed.

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 AWW, 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 AWW, 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.