H. Chronic Care Management (CCM)

As we discussed in the CY 2013 PFS final rule with comment period, we are committed to supporting primary care and we have increasingly recognized care management as one of the critical components of primary care that contributes to better health for individuals and reduced expenditure growth (77 FR 68978). Accordingly, we have prioritized the development and implementation of a series of initiatives designed to improve payment for, and encourage long-term investment in, care management services. These initiatives include the following programs and demonstrations:

- The Medicare Shared Savings Program (described in ''Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule,'' which appeared in the November 2, 2011 **Federal Register** (76 FR 67802)).
- The testing of the Pioneer ACO model, designed for experienced health care organizations (described on the Centers for Medicare and Medicaid Innovation's (Innovation Center's) website at http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/index.html).
- The testing of the Advance Payment ACO model, designed to support organizations participating in the Medicare Shared Savings Program (described on the Innovation Center's website at http://innovation.cms.gov/initiatives/Advance-Payment-ACO-Model/).
- The Primary Care Incentive Payment (PCIP) Program (described on the CMS website at www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/PCIP-2011-Payments.pdf).
- The patient-centered medical home model in the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration designed to test whether the quality and coordination of health care services are improved by making advanced primary care practices more broadly available

(described on the CMS website at www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/mapcpdemo_Factsheet.pdf).

- The Federally Qualified Health Center (FQHC) Advanced Primary Care Practice demonstration (described on the CMS website at http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/Downloads/FQHC_APCP_Demo_FAQsOct2011.pdf and the Innovation Center's website at www.innovations.cms.gov/initiatives/FQHCs/index.html).
- The Comprehensive Primary Care (CPC) initiative (described on the Innovation Center's website at http://innovations.cms.gov/initiatives/Comprehensive-Primary-Care-Initiative/index.html). The CPC initiative is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care in certain markets across the country.

In addition, HHS leads a broad initiative focused on optimizing health and quality of life for individuals with multiple chronic conditions. HHS's Strategic Framework on Multiple Chronic Conditions outlines specific objectives and strategies for HHS and private sector partners centered on strengthening the health care and public health systems; empowering the individual to use self-care management with the assistance of a healthcare provider who can assess the patient's health literacy level; equipping care providers with tools, information, and other interventions; and supporting targeted research about individuals with multiple chronic conditions and effective interventions. Further information on this initiative is available on the HHS website at http://www.hhs.gov/ash/initiatives/mcc/index.html.

In coordination with all of these initiatives, we also have continued to explore potential refinements to the PFS that would appropriately value care management within Medicare's statutory structure for fee-for-service physician payment and quality reporting. For example, in

the CY 2013 PFS final rule with comment period, we adopted a policy to pay separately for care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital stay to care furnished by the beneficiary's primary physician in the community (77 FR 68978 through 68993).

In the CY 2014 PFS final rule with comment period, we finalized a policy to pay separately for care management services furnished to Medicare beneficiaries with two or more chronic conditions beginning in CY 2015 (78 FR 74414).

1. Valuation of CCM Services – GXXX1

CCM is a unique PFS service designed to pay separately for non-face-to-face care coordination services furnished to Medicare beneficiaries with multiple chronic conditions. (See 78 FR 74414 for a more thorough discussion of the beneficiaries for whom this service may be billed and the scope of service elements.) In the CY 2014 PFS final rule with comment period, we indicated that, to recognize the additional resources required to furnish CCM services to patients with multiple chronic conditions, we were creating the following code to use for reporting this service (78 FR 74422):

- GXXX1 Chronic care management services furnished to patients with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; 20 minutes or more; per 30 days.

Although this service is unique in that it was created to separately pay for care management services, other codes include care management components. To value CCM, we compared it to other codes that involve care management. In doing so, we concluded that the CCM services were similar in work (time and intensity) to that of the non-face-to-face portion of

the lower level code for transitional care management (TCM) services (CPT code 99495 (Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge Medical decision making of at least moderate complexity during the service period face-to-face visit, within 14 calendar days of discharge)). Accordingly, we based the proposed inputs on the non-face-to-face portion of CPT code 99495.

Specifically, we proposed a work RVU for GXXX1 of 0.61, which is the portion of the work RVU for CPT code 99495 that remains after subtracting the work attributable to the face-to-face visit. (CPT code 99214 (Office/outpatient visit est) was used to value CPT code 99495, which has a work RVU of 1.50). Similarly, we proposed a work time of 15 minutes for HCPCS code GXXX1 for CY 2015 based on the time attributable to the non-face-to-face portion of CPT 99495.

For direct PE inputs, we proposed 20 minutes of clinical labor time. As established in the CY 2014 PFS final rule with comment period, in order to bill for this code, at least 20 minutes of CCM services must be furnished during the 30-day billing interval (78 FR 74422). Based upon input from stakeholders and the nature of care management services, we believed that many aspects of this service will be provided by clinical staff, and thus, clinical staff would be involved in the typical service for the full 20 minutes. CPT code 99495 has 45 minutes of non-face-to-face clinical labor time and we assumed the typical case for CCM would involve 20 minutes based upon the code descriptor and a broad eligible population that would require limited monthly services. The proposed CY 2015 direct PE input database reflected the input of 20 minutes of clinical labor time and is available on the CMS website under the supporting data files for the CY 2015 PFS proposed rule at http://www.cms.gov/Medicare/Medicare-Fee-for-

Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. The resulting proposed PE RVUs were 0.57 for CCM furnished in non-facility locations and 0.26 for CCM furnished in a facility.

The proposed MP RVU of 0.04 was calculated using the weighted risk factors for the specialties that we believed would furnish this service. We believed the proposed malpractice risk factor would appropriately reflect the relative malpractice risk associated with furnishing CCM services.

We received many public comments on our proposed valuation. In general, the commenters commended CMS for ongoing recognition of the value of non-face-to-face time expended by physicians and staff to improve outcomes for beneficiaries with chronic conditions, and the proposal to pay separately for the non-face-to-face services. However, the commenters generally believed the proposed valuation for CCM services underestimated the resources involved with complex beneficiaries, and recommended various alternatives for valuing the services. We summarize these comments in the following paragraphs.

Comment: Several commenters noted that the CPT Editorial Panel created a new code for CY 2015 that is extremely similar to the G-code we developed to report these services. These commenters suggested that we use the new CPT code 99490 (Chronic care management services, 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:

- 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).

Many of these commenters expressed a preference for the "per calendar month" used in the CPT descriptor to the "per 30 days" used in the G-code. The commenters said a calendar month rather than 30 days would be less complex administratively.

Response: It is our preference to use CPT codes unless Medicare has a programmatic need that is not met by the CPT coding structure. Accordingly, in the CY 2014 final rule with comment period we indicated that we would consider using a CPT code if one was created that reflected the service we were describing with the G-code. We believe that the new CPT code 99490 appropriately describes CCM services for Medicare beneficiaries.

We had used 30 days rather than a calendar month as the service period for the G-code so that the number of days in the service period would not vary based upon when CCM services were initiated for a given period. For example, if the services were initiated near the end of a calendar month, using the CPT code's period of "per calendar month" would make it harder for the practitioner to meet the required minimum time for the month and be able to bill CMM for that month.

However, after learning about the administrative difficulties that the 30-day period would create, we believe that the calendar month creates a reasonable period. Accordingly, we will adopt CPT code 99490 for Medicare CCM services, effective January 1, 2015 instead of the G code.

Comment: Several commenters suggested alternative approaches to the use of codes that describe CCM services. For example, one commenter said that the code should be for one year, with average of 20 minutes per month across the year. Another commenter was concerned about how the 20 minutes of care per month per patient will be calculated, because some patients

(those whose condition is less well controlled) will demand more attention and care than average patients, while those whose condition is well controlled might require very little attention. This commenter suggested that a reasonable solution would be for the care minutes per patient per month to be calculated as an average across a number of CCM patients. The commenter added that for patients entering and exiting mid-month, the average minutes of care could be calculated on a pro rata basis which adjusts for the partial months they are eligible for CCM services. Several other commenters said that CMS should use a capitated payment methodology for CCM services in the long run, but supported CCM services using the CPT codes as valued by the RUC as a short-term transitional strategy until CMS is able to expand the per beneficiary per month care management fee under CMS's primary care demonstration initiatives to all physicians. Others commented similarly that the long-term goal is capitated payments like the demonstrations/models that better encourage population-based health management and reducing utilization.

Several commenters submitted recommendations for valuation based on their experience in CMS's Patient-Centered Medical Home multipayer initiative. Assuming CCM services are furnished by a care manager receiving an annual salary of $150,000, and taking into account a commonly accepted patient to care manager ratio of 1:150, these commenters believed that under the proposed payment rate, the average service time possible would be a ceiling of 23 minutes (not a floor of 20 minutes). Based on one tracking study of care manager activity in minutes per patient per month, they believed complex care management would require 42 minutes of face-to-face and non-face-to-face time per month. Assuming the same care manger salary and patient load, the commenters asserted that the monthly payment amount necessary to provide this amount of care would be $83 per beneficiary per month.

Response: Our proposal to pay separately for these services is part of a broader series of potential refinements to the PFS that appropriately value care management within Medicare's statutory structure for fee-for-service physician payment. We do not have statutory authority to base payment under the PFS on a recurring per beneficiary per month basis. The PFS is limited to a fee-for-service model at present, and as such we do not use capitated payment for services that may or may not be furnished in a given month. We refer the commenter and other interested stakeholders to the preceding paragraphs that describe a broader set of initiatives that are designed to improve payment for, and encourage long-term investment in, care management services, including a variety of CMS and HHS programs and demonstrations.

Comment: Many commenters recommended a higher valuation for CCM services than was proposed, with some commenters providing specific suggestions as to changes in inputs and others simply asserting that a higher payment was appropriate or necessary to achieve access or the desired benefit. One commenter recommended a payment of $75 but did not provide supporting information. Several other commenters recommended that CMS adopt the RUC-recommended values for CPT code 99490 (work time of 30 minutes, work RVU of 1.0, and 60 minutes of clinical labor time). Several commenters believed CMS should adopt the work, PE and MP RVUs for CPT code 99495, with one commenter suggesting that CMS crosswalk the PE and MP RVU from the TCM code and not just the work RVU from the code in order to equalize payment for the CCM code with a per beneficiary per month payment that is made for similar services through a state Medicaid program. Another commenter pointed out that the proposed combined MP and PE RVU of 0.61 for CCM is significantly lower than for the following similar services that cannot be billed during same period with CCM: HCPCS code G0181 (Home Healthcare Oversight) which has a combined MP and PE RVU of 1.28; HCPCS code G0182

(Hospice Care Plan Oversight) which has a combined MP and PE RVU of 1.30; CPT code 99339 (Care Plan Oversight Services) which has a combined MP and PE RVU of 0.94; and CPT code 99358 (Prolonged Services without Direct Patient Contact) which has a combined MP and PE RVU of 0.98.

Several commenters suggested that CMS's comparison with TCM, CPT code 99495, was not an appropriate comparison. One commenter asked what codes other than CPT code 99495 CMS considered as similar to CCM for purposes of CCM valuation. This commenter believed the time and intensity required for the non-face-to-face portion of CPT code 99495 is not the same as for CCM services.

Several commenters suggested that CMS should develop PE RVUs for the service using alternative methodologies than for other PFS services. For example, several commenters stated that CMS should adjust the PE RVUs to account for major infrastructure and other costs required for CCM, especially health information technology, computer equipment, 24/7 beneficiary access, extensive documentation, nursing staff and other overhead costs. One commenter believed the proposed RVUs accounted for personnel costs but not the practice expense for health information technology, workforce retooling, and analytics.

We received many public comments on the appropriate work time and direct PE inputs for clinical staff time. Most suggested that the proposed inputs for time were too low and recommended using the RUC-recommended values (work time of 30 minutes and 60 minutes of clinical labor time). Regarding clinical labor time, some commenters believed the proposed 20 minutes of clinical labor was too low, being the 25th percentile for work time in the RUC survey, and they noted the significantly higher time reported in response to the RUC survey of 60 minutes of clinical labor time. Another commenter said that assuming 20 minutes of service

time per month as typical significantly undervalues the service and questioned how CMS arrived at that number. Regarding the work time, several commenters addressed the work RVU, recommending that the proposed RVU be adjusted upwards but did not specify by how much. Several commenters noted that the RUC recommendation of 1.0 work RVU for CPT codes 99490 and 99487 (Cmplx chron care w/o pt visit) is based on median survey work times of 30 minutes and 26 minutes, respectively, for these CCM codes. (The long descriptor for CPT code 99487 is, 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).

However several commenters did not object to the proposed valuation for GXXX1 and recommended that CMS monitor payment adequacy and appropriate valuation once the code is implemented.

Response: After consideration of the various comments on the work RVUs, we continue to believe that the most appropriate mechanism for determining the appropriate work RVU for this service is by using the non-face-to-face portion of the lower level TCM code, CPT code 99495. We continue to believe that the work and intensity for CCM services furnished to the eligible beneficiaries is comparable to the work and intensity involved in furnishing the non-

face-to-face portion of the service described by CPT code 99495. Therefore, we believe that using CPT code 99495 as the comparison code assures appropriate relativity with other similar services. The services suggested by the commenters as comparable to the CCM code require significantly more time. CPT code 99358 is for an hour of non-face-to-face time and has a work time of 60 minutes. CPT code 99339 has a work time of 40 minutes and is furnished to a significantly different patient population (those in a domiciliary or rest home). HCPCS codes G0181 and G0182 have work time of almost 60 minutes and also are furnished to significantly different patient populations.

We appreciate commenters' concerns regarding the various kinds of practice expense and malpractice liability costs that practices incur as they manage beneficiaries requiring CCM services. However, we continue to believe that our established PE and MP methodology used to value the wide ranges of services across the PFS assures that we have the appropriate relativity in our payments.

Although many commenters recommended that we use the time from the RUC survey of 60 minutes of clinical labor and 30 minutes of work time, we believe that since CCM is a new separately billable service, the survey data may be less reliable as the practitioners would have no experience with the code. Since at least 20 minutes of services are required to be furnished in order to report the service and our information, including comments, suggests that many beneficiaries who meet Medicare's criteria for CCM services would not need more than the minimum required minutes of service, we believe 60 minutes would overestimate the typical number of clinical labor minutes during one month for the typical eligible beneficiary. Accordingly, we are finalizing our proposed work and clinical labor times.

Comment: A number of commenters recommended that coinsurance should not apply to

CCM services. These commenters were concerned that the $8 estimated coinsurance amount in the proposed rule would hinder beneficiary access. Several commenters believed that CCM is a preventive service that should be exempt from beneficiary cost sharing. They noted that cost-sharing will make it challenging to reach the 20 minutes required for billing, because beneficiaries will delay care until face-to-face is necessary

Response: CCM services do not fall into any of the statutory preventive services benefit categories of the Act. The Secretary has the authority to add "additional preventive services" that, among other things, have been assigned an "A" or "B" rating by the United States Preventive Services Task Force, but CCM has not earned such a rating. Since CCM does not meet the criteria, we cannot designate it as an additional preventive service under section 1861(s)(2)(BB) of the Act. Further, we do not have other statutory authority that would allow us to waive the applicable coinsurance for CCM services. As discussed in the CY 2014 PFS final rule with comment period (78 FR 74424), in order to assure that beneficiaries are aware of the coinsurance for this non-face-to-face service, we are requiring that providers explain to beneficiaries the cost-sharing obligation involved in receiving CCM services and obtain their consent prior to furnishing the service. Practitioners should explain that a likely benefit of agreeing to receive CCM services is that although cost-sharing applies to these services, CCM services may help them avoid the need for more costly face to face services that entail greater cost-sharing.

Comment: Most of the commenters were concerned that the proposed payment would not be adequate for beneficiaries with complex needs who would benefit the most from CCM services. Most of the commenters recommended that we adopt more than one code to provide differential payment for more and less complex beneficiaries, using CPT CCM codes, G-code(s)

or some combination thereof. Many commenters distinguished between beneficiaries that require significantly different clinical resources--those needing "complex chronic care management" and those needing only "standard chronic care or disease management." Some commenters asserted that there is a disconnect between the code descriptor for GXXX1 and the Medicare CCM scope of service, such that ambiguity in the descriptor will result in use of GXXX1 to treat a very broad spectrum of beneficiaries inconsistent with the scope of service that the commenters believed was consistent with beneficiaries with more complex needs. They believed the proposed payment amount is appropriate for beneficiaries on needing only standard chronic care management, but would significantly underpay for beneficiaries requiring complex chronic care management.

Many commenters recommended that CMS adopt the three CPT codes describing chronic care management. In addition to the CPT code that is similar to the G-code described above (CPT code 99490), there are two additional complex chronic care coordination codes (a base code and an add-on code). Since CY 2013 when the complex chronic care coordination codes became available, CMS has bundled these codes. The base code is CPT code 99487 (Cmplx chron care w/o pt visit), and the add-on is CPT code 99489 (Complex chronic care coordination services; 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).

Other commenters recommended using two codes to describe CCM for different patient populations, or a base code and an add-on code to describe CCM for a single patient population. Some commenters recommended adoption of GXXX1 or CPT code 99490, plus CPT code 99487 along with the RUC-recommended values, to describe CCM for the two distinct populations that

require different services. These commenters stated that there is no "typical" patient that characterizes both groups of patients, and that a large number of eligible beneficiaries (those having 2 or more chronic conditions) have serious mental health and/or substance abuse disorders and would benefit greatly from CCM services). Other commenters recommended using two G-codes, one being an add-on code for each additional 20 minutes or other time spent caring for a beneficiary with more complex needs. One commenter urged CMS to adopt an add-on code for time increments over 60 minutes. Several commenters recommended a cap on additional minutes, particularly if CMS finalizes an applicable beneficiary coinsurance for CCM services. One commenter recommended that we finalize the proposed valuation for GXXX1, also recognize CPT code 99490 (Chron care mgmt srvc 20 min) with a higher payment amount, and then collect data on the impacts of differential payment amounts.

Other commenters recommended that CMS adopt CPT code 99487 (Cmplx chron care w/o pt visit) with the scope of services for GXXX1. One commenter recommended that CMS redefine its requirements and the scope of services for GXXX1 to be more consistent with chronic disease management, using CPT code 99487. The commenter believed we should adopt CPT code 99487 with the RUC-recommended valuation. One commenter more generally recommended that CMS adopt a higher intensity code for patients requiring 45-60 minutes or more of clinical staff time for assessment, medication management, care planning, coordination, education and advocacy.

Response: At this time, we believe that Medicare beneficiaries with two or more chronic conditions as defined under the CCM code can benefit from care management and want to make this service available to all such beneficiaries. Like all services, we recognize that some beneficiaries will need more services and some less, and thus we pay based upon the typical

service. However all scope of service elements apply for delivery of CCM services to any eligible Medicare beneficiary. We will evaluate the utilization of this service to evaluate what types of beneficiaries receive the service described by this CPT code, what types of practitioners are reporting it, and consider any changes in payment that may be warranted in the coming years. We are maintaining the status indicator "B" (Bundled) for CY 2015 for the complex care coordination codes, CPT codes 99487 and 99489.

Comment: Several commenters requested that CMS create codes specific to remote patient biometric monitoring (recording vital signs and other physiological data and transmitting real-time data to physicians). Several commenters requested codes specific to or inclusive of certain hematology, nephrology, endocrine and allergy/immunology conditions, such as chronic kidney disease, end-stage renal disease, diabetes and severe asthma. One commenter recommended that CMS delay implementation of this service for CY 2015 and propose for CY 2016 specific complex chronic care codes for each of the major chronic diseases, especially diabetes.

Response: We are not convinced that the care management services are sufficiently unique based upon the beneficiary's specific chronic conditions to warrant separate codes, especially given the beneficiary must have at least two chronic conditions. As noted above, we will be monitoring this service and will consider making changes if they appear warranted.

After consideration of the comments received on this proposal, we are finalizing the proposal with the following modification. Rather than creating a G-code we are adopting the new CPT code, 99490, to describe CCM services effective January 1, 2015. We intend to evaluate this service closely to assess whether the service is targeted to the right population and whether the payment is appropriate for the services being furnished. As part of our evaluation,

we will consider the whether this new service meets the care coordination needs of Medicare beneficiaries and if not how best to address the unmet needs.

2. CCM and TCM Services Furnished Incident to a Physician's Service under General Physician Supervision

In the CY 2014 PFS final rule with comment period (78 FR 74425 through 74427), we discussed how the policies relating to services furnished incident to a practitioner's professional services apply to CCM services. (In this discussion, the term practitioner means both physicians and NPPs who are permitted to bill for services furnished incident to their own professional services.) Specifically, we addressed the policy for counting clinical staff time for services furnished incident to the billing practitioner's services toward the minimum amount of service time required to bill for CCM services.

We established an exception to the usual rules that apply to services furnished incident to the services of a billing practitioner. Generally, under the "incident to" rules, practitioners may bill for services furnished incident to their own services if the services meet the requirements specified in our regulations at §410.26. One of these requirements is that the "incident to" services must be furnished under direct supervision, which means that the supervising practitioner must be present in the office suite and be immediately available to provide assistance and direction throughout the service (but does not mean that the supervising practitioner must be present in the room where the service is furnished). We noted in last year's PFS final rule with comment period that, because one of the required elements of the CCM service is beneficiary access to the practice 24-hours-a-day, 7-days-a-week, to address the beneficiary's chronic care needs (78 FR 74426), we expect the beneficiary to be provided with a means to make timely contact with health care providers in the practice whenever necessary to address chronic care

needs regardless of the time of day or day of the week. In those cases when the need for contact arises outside normal business hours, it is likely that the beneficiary's initial contact would be with clinical staff employed by the practice (for example, a nurse) and not necessarily with a practitioner. Under these circumstances, it would be unlikely that a practitioner would be available to provide direct supervision of the service.

Therefore, in the CY 2014 PFS final rule with comment period, we created an exception to the generally applicable requirement that "incident to" services must be furnished under direct supervision. Specifically, we finalized a policy to require only general, rather than direct, supervision when CCM services are furnished incident to a practitioner's services outside of the practice's normal business hours by clinical staff who are direct employees of the practitioner or practice. We explained that, given the potential risk to beneficiaries that the exception to direct supervision could create, we believed that it was appropriate to design the exception as narrowly as possible (78 FR 74426). The direct employment requirement was intended to balance the less stringent general supervision requirement by ensuring that there is a direct oversight relationship between the supervising practitioner and the clinical staff personnel who provide after-hours services.

In the CY 2015 PFS proposed rule, we proposed to revise the policy that we adopted in the CY 2014 PFS final rule with comment period. We also proposed to amend our regulations to codify the requirements for CCM and TCM services furnished incident to a practitioner's services. Specifically, we proposed to remove the requirement that, in order to count the time spent by clinical staff providing aspects of CCM services toward the CCM time requirement, the clinical staff person must be a direct employee of the practitioner or the practitioner's practice. (We note that the existing requirement that these services be provided by clinical staff,

specifically, rather than by other auxiliary personnel is an element of the service for both CCM and TCM services, rather than a requirement imposed by the "incident to" rules themselves.) We also proposed to remove the restriction that services provided by clinical staff under general (rather than direct) supervision may be counted only if they are provided outside of the practice's normal business hours. Under our proposed revised policy, then, the time spent by clinical staff providing aspects of CCM services can be counted toward the CCM time requirement at any time, provided that the clinical staff are under the general supervision of a practitioner and all other requirements of the "incident to" regulations at §410.26 are met.

We proposed to revise these aspects of the policy for several reasons. First, one of the required elements of the CCM service is the availability of a means for the beneficiary to make contact with health care practitioners in the practice to address a beneficiary's urgent chronic care needs (78 FR 74418 through 74419). Other elements within the scope of CCM services are similarly required to be furnished by practitioners or clinical staff. We believe that these elements of the CCM scope of service require the presence of an organizational infrastructure sufficient to adequately support CCM services, irrespective of the nature of the employment or contractual relationship between the clinical staff and the practitioner or practice. We also believe that the elements of the CCM scope of service, such as the requirement of a care plan, ensure a close relationship between a practitioner furnishing ongoing care for a beneficiary and clinical staff providing aspects of CCM services under general supervision; and that this close working relationship is sufficient to render a requirement of a direct employment relationship or direct supervision unnecessary. Under our proposal, CCM services could be furnished "incident to" if the services are provided by clinical staff under general supervision of a practitioner whether or not they are direct employees of the practitioner or practice that is billing for the

service; but the clinical staff must meet the other requirements for auxiliary personnel including those at §410.26(a)(1). Other than the exception to permit general supervision for clinical staff, the same requirements apply to CCM services furnished incident to a practitioner's professional services as apply to other "incident to" services. Furthermore, since last year's final rule, we have had many consultations with physicians and others about the organizational structures and other factors that contribute to effective provision of CCM services. These consultations have convinced us that, for purposes of clinical staff providing aspects of CCM services, it does not matter whether the practitioner is directly available to supervise because the nature of the services are such that they can be, and frequently are, provided outside of normal business hours or while the physician is away from the office during normal business hours. This is because, unlike most other services to which the "incident to" rules apply, the CCM services are intrinsically non-face-to-face care coordination services.

In conjunction with this proposed revision to the requirements for CCM services provided by clinical staff incident to the services of a practitioner, we also proposed to adopt the same requirements for equivalent purposes in relation to TCM services. As in the case of CCM, TCM explicitly includes separate payment for services that are not necessarily furnished face-to-face, such as coordination with other providers and follow-up with beneficiaries. It would also not be uncommon for auxiliary personnel to provide elements of the TCM services when the physician was not in the office. Generally, we believe that it is appropriate to treat separately billable care coordination services similarly whether in the form of CCM or TCM. We also believe that it would be appropriate to apply the same "incident to" rules that we are proposing for CCM services to TCM services. We did not propose to extend this policy to the required face-to-face portion of TCM. Rather, the required face-to-face portion of the service must still

be furnished under direct supervision.

Therefore, we proposed to revise our regulation at §410.26, which sets out the applicable requirements for "incident to" services, to permit TCM and CCM services provided by clinical staff incident to the services of a practitioner to be furnished under the general supervision of a physician or other practitioner. As with other "incident to" services, the physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the "incident to" service is based. We note that all other "incident to" requirements continue to apply and that the usual documentation of services provided must be included in the medical record.

Commenters uniformly supported our proposal to revise our regulation at §410.26, which sets out the applicable requirements for "incident to" services, to permit TCM and CCM services provided by clinical staff incident to the services of a practitioner to be furnished under the general supervision of a physician or other practitioner. Under the revised regulation, then, the time spent by clinical staff providing aspects of TCM and CCM services can be counted toward the TCM or CCM time requirement at any time, provided that the clinical staff are under the general supervision of a practitioner and all requirements of the revised "incident to" regulations at §410.26 are met.

Comment: One commenter requested guidance concerning whether (as has been the case with E/M codes) activities billed under "incident to" will not be able to also be billed under the CCM code.

Response: The purpose of our proposal was to allow elements of CCM services that are furnished by clinical staff incident to a practitioner's professional services (under the "incident to" regulations) to be included and reported as CCM services. We are not entirely clear what the

commenter is asking, but the time spent furnishing CCM services can only be counted once and for only one purpose, and each discrete service can be billed only once. Although we and our contractors provide many educational materials, practitioners who furnish Medicare covered items and services are responsible for learning how to appropriately bill each service.

Comment: One commenter urged us to revise the terminology by which we define the CCM and TCM services to reflect non-hierarchical interdisciplinary team care, rather than relying on an incident-to structure that obscures the actual provider of direct patient care. This commenter expressed concern about loss of benefits to clinicians under contract with a practice, rather than being employed by the practice. Another commenter similarly expressed concern that the expanded authorization for "general supervision" rather than "direct supervision" would provide an even greater incentive for physicians to require that any E/M service provided by an Advanced Practice Registered Nurse (APRN) in their practice be billed as "incident to" a physician's service. This could reduce transparency in billing data and diminish accountability for services for Part B beneficiaries.

Response: We do not entirely understand the basis for these concerns. We have accommodated numerous requests to include contracted employees within the scope of the "incident to" rules for purposes of counting time toward the TCM and CCM requirements. We have not otherwise proposed to revise the "incident to" and other regulations within which practitioners operate as they make decisions about whether to contract or directly employ clinical staff, or about how to bill for services provided. Although they are important within the context of the new TCM and CCM services, we believe that the revisions to our "incident to" regulation that are adopted in this final rule, are peripheral in the context of the overall employment and billing practices of physicians and group practices.

After consideration of the comments, we are finalizing our proposal to revise our regulation at §410.26, which sets out the applicable requirements for "incident to" services, to permit the CCM and non-face-to-face portion of the TCM services provided by clinical staff incident to the services of a practitioner to be furnished under the general supervision of a physician or other practitioner.

3. Scope of Services and Standards for CCM Services

In the CY 2014 final rule with comment period (78 FR 74414 through 74428), we defined the elements of the scope of service for CCM that are required for a practitioner to bill Medicare for the CCM service. In addition, we indicated that we intended to develop standards for practices that furnish CCM services to ensure that the practitioners who bill for these services have the capability to fully furnish them (78 FR 74415, 74418). At that time, we anticipated that we would propose these standards in the CY 2015 PFS proposed rule. We actively sought input toward development of these standards by soliciting public comments on the CY 2014 PFS final rule with comment period, through outreach to stakeholders in meetings, by convening a Technical Expert Panel, and by collaborating with federal partners such as the Office of the Assistant Secretary for Planning and Evaluation, the Office of the Assistant Secretary for Health, the Office of the National Coordinator for Health Information Technology (ONC), and the Health Resources and Services Administration. Our goal is to recognize the trend toward practice transformation and overall improved quality of care, while preventing unwanted and unnecessary care.

As we worked to develop appropriate practice standards that would meet this goal, we consistently found that many of the standards we thought were important overlapped in significant ways with the scope of service or with the billing requirements for the CCM services

that had been finalized in the CY 2014 final rule with comment period. In cases where the standards we identified were not unique to CCM requirements, we found that the standards overlapped with other Medicare requirements or other federal requirements that apply generally to health care practitioners. Based upon the feedback we received, we sought to avoid duplicating other requirements or, worse, imposing conflicting requirements on practitioners that would furnish CCM services. Given the standards and requirements that are already in place for health care practitioners and applicable to those who furnish and bill for CCM services, we decided not to propose an additional set of standards that would have to be met in order for practitioners to furnish and bill for CCM services. Instead of proposing a new set of standards applicable to only CCM services, we decided to emphasize that certain requirements are inherent in the elements of the existing scope of service for CCM services, and clarify that these must be met in order to bill for CCM services. The CCM scope of service elements finalized in the CY 2014 PFS final rule (78 FR 74414 through 74428) are as follows.

- The provision of 24-hour-a-day, 7-day-a-week access to address the patient's acute chronic care needs. To accomplish this, the patient must be provided with a means to make timely contact with health care providers in the practice to address the patient's urgent chronic care needs regardless of the time of day or day of the week.
- Continuity of care with a designated practitioner or member of the care team with whom the patient is able to get successive routine appointments.
- Care management for chronic conditions including systematic assessment of the patient'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 patient self-management of medications.

- In consultation with the patient, any caregiver and other key practitioners treating the patient, the practitioner furnishing CCM services must create a patient-centered care plan document to assure that care is provided in a way that is congruent with patient choices and values. The care plan is based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports. It is a comprehensive plan of care for all health issues, and typically includes, but is not limited to, the following elements: problem list, expected outcome and prognosis, measurable treatment goals, symptom management, planned interventions, medication management, community/social services ordered, how the services of agencies and specialists unconnected to the billing practice will be directed/coordinated, identify the individuals responsible for each intervention, requirements for periodic review and, when applicable, revision of the care plan. A full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care.

- Management of care transitions within health care, including referrals to other clinicians, follow-up after the patient's visit to an emergency department, and follow-up after discharges from hospitals, skilled nursing facilities, or other health care facilities. The practice must facilitate communication of relevant patient information through electronic exchange of a summary care record with other health care providers regarding these transitions. The practice must also have qualified personnel who are available to deliver transitional care services to the patient in a timely way so as to reduce the need for repeat visits to emergency departments and readmissions to hospitals, skilled nursing facilities or other health care facilities.

- Coordination with home and community based clinical service providers required to support the patient's psychosocial needs and functional deficits. Communication to and from

home and community based providers regarding these patient needs must be documented in the patient's medical record.

- Enhanced opportunities for the beneficiary and any relevant 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.

Similarly, we reminded stakeholders of the following additional billing requirements established in the CY 2014 final rule with comment period (in the following list, we have changed the service period from the 2015 proposed 30-day period to the final 2015 service period of one calendar month):

- Inform the beneficiary about the availability of the CCM services from the practitioner and obtain his or her written agreement to have the services provided, including the beneficiary's authorization for the electronic communication of the patient's medical information with other treating providers as part of care coordination.

- Document in the beneficiary's medical record that all elements of the CCM service were explained and offered to the beneficiary, and note the beneficiary's decision to accept or decline the service.

- Provide the beneficiary a written or electronic copy of the care plan and document in the electronic medical record that the care plan was provided to the beneficiary.

- Inform the beneficiary of the right to stop the CCM services at any time (effective at the end of a calendar month) and the effect of a revocation of the agreement to receive CCM services.

- Inform the beneficiary that only one practitioner can furnish and be paid for these services during the calendar month service period.

In one area, electronic health records (EHRs), we were concerned that the existing elements of the CCM service could leave some gaps in assuring that beneficiaries consistently receive care management services that offer the benefits of advanced primary care as it was envisioned when this service was created. It is clear that effective care management can be accomplished only through regular monitoring of the patient's health status, needs, and services, and through frequent communication and exchange of information with the patient and among the various health care practitioners and providers treating the patient. After gathering input from stakeholders through the CY 2014 rulemaking cycle, for 2015 we proposed a new scope of service element that would require use of a certified EHR and electronic care planning to furnish CCM services. We believed that requiring those who furnish CCM services to utilize EHR technology that has been certified by a certifying body authorized by the National Coordinator for Health Information Technology was necessary to ensure that key patient information is stored, shared and reconciled among the many practitioners and providers involved in managing the patient's chronic conditions, otherwise care could not be coordinated and managed. Requiring a certified EHR would enable members of the interdisciplinary care team to have immediate access to the most updated information informing the care plan. Therefore we proposed that the billing practitioner must utilize EHR technology certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the EHR certification criteria identified in the then-applicable version of 45 CFR part 170. We proposed that at a minimum, the practice must utilize EHR technology that meets the certification criteria adopted at 45 CFR 170.314(a)(3), 170.314(a)(4), 170.314(a)(5),

170.314(a)(6), 170.314(a)(7) and 170.314(e)(2) pertaining to the capture of demographics, problem lists, medications, and other key elements related to the ultimate creation of an electronic summary care record. These sections of the regulation comprise the certification criteria for specific core technology capabilities (structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary) for the 2014 edition. Under the proposal, practitioners furnishing CCM services beginning in CY 2015 would be required to utilize an EHR certified to at least these 2014 edition certification criteria. Given these 2014 edition criteria, the EHR technology would be certified to capture data and ultimately produce summary records according to the HL7 Consolidated Clinical Document Architecture standard (see 45 CFR 170.205(a)(3)).

In addition, when any of the CCM scope of service elements refers to a health or medical record, we proposed to require use of an EHR certified to at least the 2014 edition certification criteria to fulfill the scope of service element in relation to the health or medical record. As finalized in the CY 2014 PFS final rule, the scope of service elements that reference a health or medical record are:

- A full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination and ongoing clinical care.
- 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.
- Inform the beneficiary of the availability of CCM services and obtain his or her written agreement to have the services provided, including authorization for the electronic communication of his or her medical information with other treating providers. Document in the

beneficiary's medical record that all of the CCM services were explained and offered, and note the beneficiary's decision to accept or decline these services.

- Provide the beneficiary a written or electronic copy of the care plan and document in the electronic medical record that the care plan was provided to the beneficiary.

Regarding the care plan in particular, we believed that requiring practitioners furnishing CCM services to maintain and share an electronic care plan would alleviate the errors that can occur when care plans are not systematically reconciled. To ensure that practices offering CCM services meet these needs, we proposed that CCM services must be furnished with the use of an EHR or other health IT or health information exchange platform that includes an electronic care plan that is accessible to all practitioners within the practice, including being accessible to those who are furnishing care outside of normal business hours, and that is available to be shared electronically with care team members outside of the practice. This was a more limited proposal compared to our CY 2014 proposal that we did not finalize that would have required members of the chronic care team who are involved in the after-hours care of the patient to have access to the beneficiary's full electronic medical record (78 FR 74416 through 74417).

Regarding the clinical summary, we proposed to require technology certified to the 2014 edition for the electronic creation of the clinical summary, formatted according to the standard adopted at 45 CFR 170.205(a)(3), but we did not specify that this format must be used for the exchange of beneficiary information (79 FR 40367). For instance, we did not propose that practitioners billing for CCM services must adopt certified technology related to the exchange of a summary care record such as the transmission standard related to Direct Project Transport in 45 CFR 170.314(b)(2)(ii).

We indicated that we believed our proposed new scope of service element for a certified EHR and electronic care planning would ensure that practitioners billing for CCM could fully furnish the services, allow practitioners to innovate around the systems that they use to furnish these services, and avoid overburdening small practices. We indicated that we believed that allowing flexibility as to how practitioners capture, update, and share care plan information was important at this stage given the maturity of current EHR standards and other electronic tools in use in the market today for care planning.

In addition to seeking comment on this new proposed scope of service element, we sought comment on any changes to the scope of service or billing requirements for CCM services that may be necessary to ensure that the practitioners who bill for these services have the capability to furnish them and that we can appropriately monitor billing for these services. With the addition of the electronic health information technology element that we proposed, we believed that the elements of the scope of service for CCM services, when combined with other important federal health and safety regulations, would provide sufficient assurance that practitioners billing for CCM could fully furnish the services, and that Medicare beneficiaries receiving CCM would receive appropriate services. However we expressed special interest in receiving public feedback regarding any meaningful elements of the CCM service or beneficiary protections that may be missing from the scope of service elements and billing requirements.

The following paragraphs summarize the comments we received regarding these elements of the scope of service for CCM services and our responses.

Comment: Some commenters were disappointed that CMS did not propose an additional set of standards. The commenters expressed concern that there would not be sufficient accountability for high quality CCM services. Some commenters recommended further

development of standards such as inclusion of evidence-based self-management programs offered by community organizations, quality measures that engage patients and demonstrate improved outcomes, or a best practices guide to assist the physician community with implementation. However, many commenters opposed further standards, and agreed with CMS that additional standards would largely overlap with other Medicare requirements or were already reflected in the scope of service elements.

Response: We appreciate the commenters' concerns about ensuring quality of care. We continue to believe that with the addition of the EHR element, the required scope of service elements are sufficient for ensuring high quality CCM services in 2015. We note that section III.K of this final rule with comment period addresses quality measures for physicians' services, and stakeholders may submit suggestions for quality measures related to CCM in response to this section of the regulation.

Comment: Many commenters expressed broad support for our EHR proposal. The commenters commended the strong emphasis on data sharing and requirements for a robust EHR as vital to successful care coordination and continuity of care. Several commenters did not believe the proposal would pose a significant administrative burden. One commenter noted that use of an EHR would help practitioners to document the time spent furnishing CCM services.

Although commenters supported adoption of certified EHR technology (CEHRT) generally, many were concerned that an insufficient number of physicians have adopted CEHRT with the functionalities we proposed for CCM, especially interoperability with other providers. The commenters were also concerned that physicians practicing in rural or economically depressed areas would not have the resources to implement such technology and would be disqualified from furnishing separately billable CCM services. Many believed the proposal was

laudable but premature, recommending that CMS delay adoption of the 2014 EHR certification criteria for CCM services by 3 to 4 years when they will be more widely adopted, or phase in the 2014 certification criteria over 2 years as a requirement for 2017. Several commenters recommended that we finalize our proposal but provide hardship exceptions for certain smaller or rural practices to enable them to bill separately for CCM services in the absence of an interoperable EHR in certain circumstances, provide financial incentives, or allow other flexibility around the requirements for physicians who cannot meet them at this time. One commenter supported the proposal but suggested we allow aspects of CCM services to be furnished using fax and secure messaging technology if physicians encounter challenges with interoperability. Until EHR systems are interoperable, some commenters suggested allowing practitioners to attest that all requirements for billing CCM were met using CEHRT or an alternative technology, or to attest that all members of the care team have timely access (24/7 access in "real time" or "near real time") to the most updated information regarding the care plan through either electronic or non-electronic means, with ongoing efforts to implement interoperable EHRs. The commenters stated many practices are making patient information accessible in a timely manner to the entire care team, but have not yet fully implemented an interoperable EHR with other providers. Several commenters were concerned about the ability of current EHR technologies to share information across different providers and EHR systems. Commenters requested that CMS ensure that no certified EHR contains technological or business impediments to data sharing across disparate technology platforms used by multiple providers trying to coordinate care. In addition, many commenters were concerned about access to CCM services, and recommended that CMS prioritize access over adoption of CEHRT. Several

commenters stated that not all types of physicians have access to an EHR that meets the needs of their specialty.

A number of commenters stated that CCM could be (and already is) effectively provided without any EHR or a without a certified EHR, and recommended that CMS rescind the proposal or make the EHR requirement optional. These commenters disagreed with the requirement that CCM services must be furnished with use of a certified EHR, information technology (IT) platform or exchange platform that includes a care plan, with some stating that certified EHR systems have not demonstrated improvements in the management of chronic conditions, especially complex cases, and suggested postponing the care plan and other EHR requirements until they are proven effective and adopted by most providers. Others stated that an EHR was necessary and that CMS should require an EHR that promotes communication among various professional on the care team, includes the patient as part of the team, and enables clinical monitoring and effective care planning. Commenters indicated that many physicians accomplish this through generating or receiving electronic discharge summaries, clinical documentation, and patient-centered plans of care, but are not using certified technologies to carry out these functions and should not be penalized.

One commenter stated that only about half of all physicians had an EHR system with advanced functionalities in 2013, many current systems were not designed with interoperability in mind and transition costs are high. The commenter believed the proposed payment amount would not sufficiently cover the cost of purchasing or upgrading an EHR system, and requiring a certified EHR would limit the number of eligible physicians without significantly adding value to CCM services. Another commenter stated that only 1,000 physicians and other eligible health

professionals have achieved Stage 2 of Meaningful Use of certified EHR technology, compared with more than 300,000 physicians and eligible professionals who have achieved Stage 1.

Response: We continue to believe that it is necessary to require the use of EHR technology that has been certified under the ONC Health IT Certification Program as requisite for receiving separate payment for CCM services, to ensure that practitioners have adequate capabilities to allow members of the interdisciplinary care team to have timely access to the most updated information informing the care plan. We agree with commenters that health IT tools are most effective when there are no technological or business impediments to data sharing, or disparate technology platforms used by multiple providers trying to coordinate care, and that we should ensure common functionalities as much as possible across providers. However, we also agree with commenters who expressed concern that requiring the most recent edition of EHR certification criteria could be an impediment to the broad utilization of the CCM service. In response to comments, we are modifying our proposal regarding which edition of certified EHR technology will be required, in order to allow more flexibility as practitioners transition to the use of certified EHR technology. Accordingly, we are modifying our proposal to specify that the CCM service must be furnished using, at a minimum, 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 (hereinafter "CCM certified technology") to meet the final core technology capabilities (structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary). Practitioners must also use this CCM certified technology to fulfill the CCM scope of service requirements whenever the requirements reference a health or medical record. This will ensure that requirements for CCM billing under the PFS are consistent throughout each PFS payment year and are

automatically updated annually according to the certification criteria required for the EHR Incentive Programs. For CCM payment in CY 2015, this policy will allow practitioners to use EHR technology certified to either the 2011 or 2014 edition(s) of certification criteria to meet the final core capabilities for CCM and to fulfill the CCM scope of service requirements whenever the requirements reference a health or medical record. We are finalizing the separate provision we proposed for the electronic care plan scope of service element without modification as discussed below. We remind stakeholders that for all electronic sharing of beneficiary information under our final CCM policies, HIPAA standards apply in the usual manner.

Comment: Several commenters questioned the relationship between the Meaningful Use criteria and the proposed EHR scope of service element for CCM. One commenter stated that none of the requirements for EHR capability for payment of CCM services should be tied to or related to Meaningful Use, because many of the Meaningful Use requirements do not apply to CCM. Another commenter supported what they understood to be our proposal, to require billing physicians to adopt an EHR and utilize it to meet the most recent standard for Meaningful Use. However, the commenter noted (similar to the previous commenter) that the current functionalities and standards for EHR technology required for Meaningful Use are not entirely aligned with the functionalities required for CCM, for example the commenter believed that the electronic care plan need only be shared 10 percent of the time to meet Meaningful Use measures, but that CCM would require it to be available 24/7 and to all practitioners. The commenter expressed concern that practitioners might not be able to furnish CCM as envisioned by CMS due to discrepancies with the Meaningful Use criteria, and urged CMS to adopt interoperability standards for Meaningful Use that would enable successful care coordination models. Another commenter recommended that enforcement of the proposed EHR requirement

be coterminous with the enforcement of Meaningful Use Stage 2 to ensure practices have the ability to comply.

Response: Although we understand why some commenters would like for the requirements for the EHR Incentive Programs and the EHR scope of service element for CCM to be identical, we do not believe that is entirely possible because of the different nature and purpose of the respective EHR specifications. In many respects they are not comparable requirements. For example, the PFS sets payment requirements prospectively for a given calendar year, while the EHR Incentive Program may change requirements mid-year. In addition, many of the Meaningful Use measures are not relevant for the provision of CCM and we believe we should only require practitioners to adopt the certified technology that is relevant to the scope of CCM services. In their attempts to meet Meaningful Use criteria for a given year, practitioners are required to use technology certified to a specific edition(s) of certification criteria to meet the CEHRT definition, and as we discussed above we are aligning the edition required to bill CCM with the edition(s) required for Meaningful Use each year. However, it is conceivable that a practitioner could use CCM certified technology to provide and be paid for CCM in a given calendar year that will not be sufficient for achieving Meaningful Use in that same year because CCM must be furnished using at least the edition(s) of certified EHR technology required for the EHR Incentive Programs as of December 31st of the prior calendar year. Also, it is possible that a practitioner could use technology certified to an edition that qualifies for CCM payment that could also be used to achieve Meaningful Use for a given calendar year, but still not meet the objectives and associated measures of a particular stage of Meaningful Use that are required to qualify for an EHR Incentive payment or avoid a downward adjustment to payments. As the commenters noted, the Meaningful Use measures are not all

relevant to the provision of CCM services, and the practitioner may not have sufficient certified technology to support all the necessary or relevant Meaningful Use objectives and measures under the EHR Incentive Programs. Certified technology is used in different ways to meet the requirements of each program. We believe that the policy we are finalizing here aligns the CCM scope of service element to the extent appropriate with the EHR Incentive Programs to achieve maximum consistency.

Comment: Several commenters asked us to clarify the requirement for the electronic care plan in relationship to the overall requirement for a certified EHR and in relationship to the 24/7 access requirement. The commenters stated they were not sure whether these proposals were independent provisions or impacted one another. The commenters stated that if CMS intended these as independent provisions, the agency should identify objective criteria to evaluate whether a particular health IT product has adequate capabilities to meet the separate requirement for the electronic care plan. The commenters stated they were not sure whether the electronic care plan would require a certified EHR, or whether there would be an exception to use of CEHRT for the care plan. The commenters recommended flexibility in how practitioners and providers capture, develop, update and share care plan information. One commenter recommended that if practitioners must attest to use of a qualifying electronic care plan, CMS should only require a simple yes/no response to minimize billing impediments. One commenter asked us to clarify the required elements of the care plan in relation to different EHR systems.

In addition, several commenters requested that we clarify whether the care plan must be electronically accessible 24/7 to all providers treating the patient's chronic conditions, those within the billing practice, or those within the billing practice who are communicating with the patient after hours. The commenters noted that providers other than the billing practitioner may

not use the same certified EHR, so it would be unreasonable to expect the same care plan and other relevant information to be accessible to all providers at all times. Other commenters believed we proposed flexibility around the certified EHR requirement in relation to the electronic care plan, and supported this proposed flexibility.

Response: Regarding the care plan, we proposed that CCM services must be furnished with the use of an EHR or other health IT or health information exchange platform (not necessarily a certified EHR) that includes an electronic care plan that is accessible at all times to the practitioners within the practice, including those who are furnishing CCM outside of normal business hours. By practitioners "within the practice," we mean any practitioners furnishing CCM services whose minutes count towards a given practice's time requirement for reporting the CCM billing code.

In addition, we proposed that the electronic care plan must be available to be shared electronically with care team members outside the practice (who are not billing for CCM). We sought to convey that practitioners could satisfy these requirements related to the care plan without using the certified EHR technology. We specified that the certified EHR technology is only required to accomplish activities described in the scope of service elements that specifically mention a medical record or EHR. We said that a full list of problems, medications and medication allergies in the certified EHR (which would follow structured recording formats) must inform the care plan, not that the care plan itself must be created or transmitted among providers using certified EHR technology. We note that this was a limited proposal compared to our CY 2014 proposal that we did not finalize that would have required members of the chronic care team who are involved in the after-hours care of the patient to have access to the patient's full electronic medical record instead of just the care plan (78 FR 74416 through 74417).

Through separate requirements for the electronic care plan and the certified EHR, our intent was to require practitioners to use some form of electronic technology tool or service in fulfilling the care plan element (other than facsimile transmission), recognizing that certified EHR technology is limited in its ability to support electronic care planning at this time, and that practitioners must have flexibility to use a wide range of tools and services beyond certified EHR technology now available in the market to support electronic care planning. We intended that all care team members furnishing CCM services that are billed by a given practice (contributing to the minimum time required for billing) must have access to the electronic care plan at all times when furnishing CCM services. However, the electronic care plan would not have to be available at all times to other non-billing practices, recognizing that other practices may not be using compatible electronic technology or participating in a health information exchange.

We are finalizing the electronic care plan and 24/7 access elements as proposed, clarifying that to satisfy the care plan scope of service element, practitioners must electronically capture care plan information and make this information available to all care team members furnishing CCM services that are billed by a given practice (counting towards the minimum monthly service time), even when furnishing CCM outside of normal business hours. In addition, practitioners must electronically share care plan information as appropriate with other providers and practitioners who are furnishing care to the patient. We are not requiring that practitioners use a specific electronic technology to meet the requirement for 24/7 access to the care plan or its transmission, only that they use an electronic technology other than facsimile. For instance, practices may satisfy the 24/7 care plan access requirement through remote access to an EHR, web-based access to a care management application, or web-based access to a health information exchange service that captures and maintains care plan information. Likewise, we

are not requiring that practitioners use a specific electronic technology to meet the requirement to share care plan information electronically with other practitioners and providers who are not billing for CCM. For instance, practitioners may meet this sharing requirement through the use of secure messaging or participation in a health information exchange with those practitioners and providers, although they may not use facsimile transmission.

While we are not requiring that practitioners use a specific electronic technology at this time (other than not allowing facsimile), we may revisit this requirement as standards-based exchange of care plan information becomes more widely available in the future. We remind stakeholders that for all electronic sharing of beneficiary information under our final CCM policies, HIPAA standards apply in the usual manner.

Comment: Several commenters asked us to clarify the relationship between the certified EHR proposal and the summary record exchange requirement. Commenters believed that CMS had cited specific regulatory provisions around exchange in the proposed rule (identified by the commenter as a Summary Record Exchange (SRE) capability tag, referring to a designation used to identify those products on the Certified Health IT Product List maintained by ONC offering technology certified to criteria around the exchange of summary care records) and should consider alternatives. The commenters were not clear as to whether they objected to what they believed to be the proposed format or the transmission method of the summary record exchange.

Response: In the CY 2014 PFS final rule with comment period, as part of the care transitions management scope of service element, we indicated that the practice must be able to facilitate the communication of relevant patient information through electronic exchange of a summary care record with other health care providers (78 FR 74418). We did not specify a standard for the "summary care record" that providers must exchange electronically, nor did we

specify a method by which providers must facilitate the communication of beneficiary information, such as use of certified EHR technology. In the CY 2015 PFS proposed rule (79 FR 40367), we proposed that the practitioner must utilize EHR technology certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the EHR certification criteria identified in the then-applicable version of 45 CFR part 170. Under one of the specific certification criteria cited, we proposed that practitioners must use technology that meets the criterion adopted at §170.314(e)(2), which would ensure that they produce summary records formatted according to the standard adopted at §170.205(a)(3). However, we did not propose that this formatting standard must be used for the exchange of patient information, only that in furnishing CCM services, practitioners must format their summaries according to this standard. We did not propose that providers billing for CCM services must adopt any certified technology for the exchange of a summary care record, such as the transmission standard related to Direct Project Transport in § 170.314(b)(2)(ii). We recognized that providers are currently exchanging patient information to support transitions of care in a variety of meaningful ways beyond the methods specified with 2014 edition certified technology, with the exception of faxing which would not meet the proposed scope of service requirement. The 2014 edition sets specific requirements for transmission or exchange of the summary record that technology must meet for certification, and we expected that only some practitioners could adopt and use such technology in CY 2015. Therefore we did not constrain practitioners to the exchange functionality in the 2014 edition if they utilized an alternative electronic tool.

As discussed above, our final policy will allow practitioners billing the PFS for CCM services to use the edition(s) of certification criteria that is acceptable for the EHR Incentive Programs as of December 31st of each calendar year preceding each PFS payment year to meet

the final core technology capabilities (structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary). (Also practitioners must use this CCM certified technology to fulfill the CCM scope of service requirements whenever the requirements reference a health or medical record). Under this final policy, practitioners must format their structured clinical summaries according to, at a minimum, the standard that is acceptable for the EHR Incentive Programs as of December 31st of the calendar year preceding each PFS payment year.

We are finalizing our proposal that practitioners must communicate relevant patient information through electronic exchange of a summary care record to support transitions of care, with a clarification that practitioners do not have to use any specific content exchange standard in CY 2015. We did not propose and are not finalizing a requirement to use a specific tool or service to communicate beneficiary information, as long as providers do so electronically. We note however that faxing will not fulfill this requirement for exchange of the summary care record. We did not propose to modify our view, discussed in the CY 2014 PFS final rule with comment period, that practitioners furnishing and billing for CCM services must be able to support care transitions through the electronic exchange of beneficiary information in a summary care record (78 FR 74418). While certain 2014 edition certification criteria address a content standard and transmission method for exchange of a summary record, we continue to expect that only some practitioners could adopt and use such technology. Moreover, we recognize that providers are currently exchanging patient information to support transitions of care in a variety of meaningful ways beyond the methods specified in 2014 edition certification criteria. We continue to believe that at least for CY 2015, we should allow flexibility in the selection of the electronic tool or service that is used to transmit beneficiary information in support of care

transitions, as long as practitioners electronically share beneficiary information to support transitions of care. Finally we remind stakeholders that for all electronic sharing of beneficiary information under our final CCM policies, HIPAA standards apply in the usual manner.

Comment: Several commenters expressed concern about requiring a certified EHR for billing CCM. The commenters were concerned that CMS would not allow the use of non-certified technologies that may be more innovative and effective than certified technologies. Commenters requested that we clarify whether only the certified EHR (and no other electronic tool) could be used to conduct CCM services, for example the use of enhanced communication methods other than telephone. One commenter stated that many times the practice will be using the certified EHR system to carry out such activities, and there are strong Meaningful Use incentives to employ the certified EHR for these activities. However, a practice may also have other capabilities and tools that would support elements of the CCM services. These commenters asked us to clarify whether the requirement to utilize certified EHR technology is a literal statement that only certified EHR technology may be used in furnishing the scope of service elements for CCM services.

Response: We continue to believe that health IT tools are most effective when there are no technological or business impediments to data sharing, or disparate technology platforms used by multiple practitioners trying to coordinate care. For the separately billable CCM service, we believe it is necessary to establish as part of the scope of the service a certified EHR that allows for the data capture, accessibility and sharing capabilities necessary to furnish the service. Therefore, we are finalizing our proposal to require use of CCM certified technology to meet the final core technology capabilities (structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary). In addition, whenever a

scope of service element references a health or medical record, CCM certified technology must be used to fulfill that scope of service element in relation to the health or medical record. We have listed above the current scope of service elements that include a reference to a health or medical record. If both CCM certified technology and other methods are available to the practitioner to fulfill the final core technology capabilities for CCM (structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary) or the CCM scope of service elements referencing a the health or medical record, practitioners may only use the certified capability. We remind stakeholders that for all electronic sharing of beneficiary information under our final CCM policies, HIPAA standards apply in the usual manner.

Comment: One commenter recommended that we adopt the following additional 2014 EHR certification criteria:

- Patient List Creation (45 CFR 170.314(a)(14)), which would support the required element of service for preventive services and routine appointments, and could help provide registry types of functions for the practice to use in managing patients who have agreed to participate in the chronic care management service.
- Patient-Specific Education Resources (§170.314(a)(15)), which would help assure the ability to provide the patient with relevant educational materials about their chronic disease conditions.
- Clinical Reconciliation (§170.314(b)(4)), which would serve support the medication reconciliation requirement and the requirement to review patient adherence to their medication regime.
- View/Download/Transmit to a 3rd Party (§170.314(e)(1)), which would enable

patients to access their own electronic health record and have access to information related to their care at their own convenience.

- Secure Messaging, Ambulatory Setting Only (§170.314(e)(3)).

Response: Some of these 2014 certification criteria are not relevant (have no corollary) in the 2011 certification criteria, so we would not require them because practitioners are not required to use the 2014 edition in CY 2015. In addition, we are requiring that providers use certified EHR technology to fulfill a limited number of the scope of service elements (summarized in Table 33). We are requiring the certified technology only for certain foundational elements, and believe we should avoid making the EHR requirement for CCM unnecessarily complex at this time. While we agree that the other features of certified EHR products mentioned by the commenter would certainly help many practitioners fulfill the other elements of the CCM service, practitioners may be using tools other than certified technology that are adequate for the required task(s), for example, registry tools for patient list creation, educational resources, patient portals, third party reconciliation services, and secure messaging systems.

Comment: We received many comments on the scope of service elements other than the EHR, some requesting that we implement additional standards. A few commenters said CMS should consider adding a requirement for use of community based providers through a home visit at least once every 12 months to assess the home environment and the need for community based resources, or that CMS should include home and domiciliary care, group visits and community based care. Several commenters wanted us to include "remote patient monitoring" or "patient generated health data" in the scope of services, such as daily remote monitoring of physiology and biometrics. Several commenters recommended additional tools for patient self-management

education and training, or "patient activation" tools. One commenter recommended we require a patient experience survey to assess the patient's perspective regarding the CCM services they receive. Several commenters believed we should expand the medication management and medication reconciliation element to include more comprehensive medication management and more clearly define "review of adherence" to the medication regimen.

Response: Other than the scope of service element for EHR and other electronic technology, we do not believe additional changes to the scope of service elements for CCM are warranted at this time. We are requiring certified EHR technology for certain foundational or "core" elements, including structured recording of medications and medication allergies. As finalized in the scope of service in the CY 2014 PFS final rule with comment period we are also requiring medication reconciliation with review of adherence and potential interactions, and oversight of patient self-management of medications. We believe it would be overly burdensome, especially given the broad eligible beneficiary population and final RVU inputs, to include more specific requirements related to medication management, especially when greater specificity is likely not necessary to ensure adequate care. The CCM services are by definition non-face-to-face services; therefore we are not including a requirement for home or domiciliary visits or community based care (although there is a requirement related to coordinating home and community based care). Practitioners who engage in remote monitoring of patient physiological data of eligible beneficiaries may count the time they spend reviewing the reported data towards the monthly minimum time for billing the CCM code, but cannot include the entire time the beneficiary spends under monitoring or wearing a monitoring device. If we believe changes to the scope of service elements are warranted in the future, we will propose them through notice and comment rulemaking taking the comments we received to date into consideration.

<u>Comment</u>: We received many comments on the scope of service elements other than the EHR, requesting that CMS implement fewer standards. Some commenters believed that other than the "incident to" provisions, the scope of service elements are administratively burdensome and it will be difficult for physicians to adequately document that they have fulfilled the requirements. Several commenters did not believe it was necessary to require written beneficiary consent. Others asked that CMS develop model beneficiary consent forms.

<u>Response</u>: We understand the commenters' concerns about adequate documentation, although this issue is not unique to CCM services. We believe the additional scope of service element for the EHR and electronic sharing of the care plan and clinical summary record will create an electronic "footprint" that will facilitate documentation, including documentation of the minimum monthly amount of time spent in providing CCM services.

Regarding beneficiary consent, we believe written beneficiary consent and its documentation in the medical record is necessary because we are requiring practices to share beneficiaries' protected health information both within and outside of the billing practice in the course of furnishing CCM services and because beneficiaries will be required to pay coinsurance on non-face-to-face services. We do not believe the content or nature of the required consent is so complex that we should develop model formats. If we believe changes to the scope of service elements are warranted in the future, we will propose them through notice and comment rulemaking taking the comments we received to date into consideration.

In summary, we are finalizing our proposal for the CCM scope of service element for EHR technology as proposed, with the following modification. We are including as an element of the separately billable CCM service the use of, at a minimum, technology certified to the edition(s) of certification criteria that is acceptable for the EHR Incentive Programs as of