G. 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 Center 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 two or more chronic conditions. (See 78 FR 74414 for a more complete description of the beneficiaries for whom this service may be billed.) In the CY 2014 PFS final rule with comment period, we indicated that, to recognize the additional resources required to provide 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 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 used the work RVU and work time associated with the non-face-to-face portion of CPT code 99495 as a foundation to determine our proposed values for CCM services. Specifically, we are proposing 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 are proposing 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. The work time file associated with this PFS proposed rule is available on the CMS website in the Downloads section for the CY 2015 PFS proposed rule at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

For direct PE inputs, we are proposing 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 believe that many aspects of this service will be provided by clinical staff, and thus, clinical staff will be involved in the typical service for the full 20 minutes. The proposed CY 2015 direct PE input database reflects this input 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 proposed PE RVUs included in Addendum B to this proposed rule reflect the RVUs that result from using these inputs to establish PE RVUs.

The proposed MP RVU was calculated using the weighted risk factors for the specialties that we believe will furnish this service. We believe this malpractice risk factor appropriately reflects the relative malpractice risk associated with furnishing CCM services. The MP RVU included in Addendum B of this proposed rule reflects the RVU that results from the application of this proposal.

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 (75 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 the availability to a beneficiary 24-hours-a-day, 7-days-a-week to address the patient's chronic care needs (78

FR 74426) that 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 patient'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 patients 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 this rule, we are proposing to revise the policy that we adopted in the CY 2014 PFS final rule with comment period, and to amend our regulations to codify the requirements for CCM services furnished incident to a practitioner's services. Specifically, we are proposing 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 are also proposing 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 requirements of the "incident to" regulations at §410.26 are met.

We are proposing 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 patient'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" under general supervision if the auxiliary personnel providing the services in conjunction with CCM services are clinical staff, and whether or not they are direct employees of the

practitioner or practice billing for the service; but the clinical staff must meet the requirements for auxiliary personnel contained in §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 are also proposing 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 patients. 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 are not proposing to extend this policy to the E/M service that is a required element of TCM. Rather, the required E/M service must still be furnished under direct supervision.

Therefore, we are proposing 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 documentation of services provided must be included in the medical record.

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 services required in order for a practitioner to bill Medicare for CCM services. 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 this 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, 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 had 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 already in place for health care practitioners and that will apply to those who furnish and bill for CCM services, we have decided not to propose an additional set of standards that must 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 have 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.

In one area – that of electronic health records – we are 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 beneficiary and among health care practitioners treating the beneficiary. As a part of the CY 2014 PFS final rule with comment period (78 FR 43338 through 43339), we specified that the electronic health record for a patient receiving CCM services should include a full list of problems, medications and medication allergies in order to inform the care plan, care coordination, and ongoing clinical

care. Furthermore, those furnishing CCM services must be able to facilitate communication of relevant patient information through electronic exchange of a summary care record with other health care providers as a part of managing health care transitions. We believe that if care is to be coordinated effectively, all communication must be timely, and it must include the information that each team member needs to know to furnish care that is congruent with a patient's needs and preferences. In addition, those furnishing CCM services need to establish reliable flows of information from emergency departments, hospitals, and providers of post-acute care services to track their CCM patients receiving care in those settings. Reliable information flow supports care transitions, and can be used to assess the need for modifications of the care plan that will reduce the risk of readmissions, increased morbidity, or mortality.

After gathering input from stakeholders, we believe that requiring those who furnish CCM services to utilize electronic health record technology that has been certified by a certifying body authorized by the National Coordinator for Health Information Technology will ensure that practitioners have adequate capabilities to allow members of the interdisciplinary care team to have immediate access to the most updated information informing the care plan. Furthermore, we believe that requiring those that furnish CCM services to maintain and share an electronic care plan will alleviate the development of duplicative care plans or updates and the associated errors that can occur when care plans are not systematically reconciled. To ensure that practices offering CCM services meet these needs, we are proposing a new scope of service requirement for electronic care planning capabilities and electronic health records. Specifically, we are proposing that CCM services must be furnished with the use of an electronic health record or other health IT or health information exchange platform that includes an electronic care plan that is accessible to all providers 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. To ensure all practices have adequate capabilities to meet electronic health record requirements, 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 electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170. 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. For example, practitioners furnishing CCM services beginning in CY 2015 would be required to utilize an electronic health record certified to at least those 2014 Edition certification criteria. Given these certification criteria, 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)). When any of the CCM scope of service requirements include a reference to a health or medical record, a system meeting these requirements is required.

We believe this scope of service element will ensure that practitioners have adequate capabilities to fully furnish CCM services, allow practitioners to innovate around the systems that they use to furnish these services, and avoid overburdening small practices. We believe that allowing flexibility as to how providers capture, update, and share care plan information is important at this stage given the maturity of current electronic health record 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 are seeking 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.

To assist stakeholders in commenting, we remind you of the elements of the current scope of service for CCM services that are required in order for a practitioner to bill Medicare for CCM services as finalized in the CY 2014 final rule with comment period. We would note that additional explanation of these elements can be found at 78 FR 74414 through 74428. The CCM service includes:

- Access to care management services 24-hours-a-day, 7-days- a-week, which means providing beneficiaries 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 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.

- Creation of a patient-centered care plan document to assure that care is provided in a way that is congruent with patient choices and values. A plan of care 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.

- Management of care transitions between and among health care providers and settings, including referrals to other clinicians, follow-up after a beneficiary visit to an emergency department, and follow-up after discharges from hospitals, skilled nursing facilities, or other health care facilities.

- Coordination with home and community based clinical service providers as appropriate to support a beneficiary's 's psychosocial needs and functional deficits.

- Enhanced opportunities for a 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 remind stakeholders that in the CY 2014 final rule, we established particular billing requirements for CCM services that require the practitioner to:

- 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 patient's medical record that all of the CCM services were explained and offered to the patient, 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.

- Inform the beneficiary of the right to stop the CCM services at any time (effective at the end of a 30-day period) and the effect of a revocation of the agreement on CCM services.

- Inform the beneficiary that only one practitioner can furnish and be paid for these services during the 30-day period.

With the addition of the electronic health record element that we are proposing, we believe that these elements of the scope of service for CCM services, when combined with other important federal health and safety regulations, provide sufficient assurance that Medicare beneficiaries receiving CCM services will receive appropriate services. However, we remain

interested in receiving public feedback regarding any meaningful elements of the CCM service or beneficiary protections that may be missing from these scope of service elements and billing requirements. We encourage commenters, in recommending additional possible elements or safeguards, to provide as much specific detail as possible regarding their recommendations and how they can be applied to the broad complement of practitioners who may furnish CCM services under the PFS.

4. Payment of CCM Services in CMS Models and Demonstrations

As discussed above, several CMS models and demonstrations address payment for care management services. The Multi-payer Advanced Primary Care Practice Demonstration and the Comprehensive Primary Care Initiative both include payments for care management services that closely overlap with the scope of service for the new chronic care management services code. In these two initiatives, primary care practices are receiving per beneficiary per month payments for care management services furnished to Medicare fee-for-service beneficiaries attributed to their practices. We propose that practitioners participating in one of these two models may not bill Medicare for CCM services furnished to any beneficiary attributed to the practice for purposes of participating in one of these initiatives, as we believe the payment for CCM services would be a duplicative payment for substantially the same services for which payment is made through the per beneficiary per month payment. However, we propose that these practitioners may bill Medicare for CCM services furnished to eligible beneficiaries who are not attributed to the practice for the purpose of the practice's participation as part of one of these initiatives. As the Innovation Center implements new models or demonstrations that include payments for care management services, or as changes take place affecting existing models or demonstrations, we will address potential overlaps with CCM and seek to implement appropriate reimbursement policies. We welcome comments on this proposal. We also solicit comments on the extent to

which these services may not actually be duplicative and, if so, how our reimbursement policy could be tailored to address those situations.