

September 6, 2013

**Marilyn B. Tavenner**

**Administrator**

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-1600-P  
Mail Stop C4-26-05  
7500 Security Boulevard,  
Baltimore, Maryland 21244-1850.

**Re: Medicare Programs: Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule and Other Revisions to Part B for CY 2014 (CMS–1690–P)**

Dear Ms. Tavenner:

The undersigned medical specialty societies are writing to express our gratitude to CMS for its support of the Complex Chronic Care Management (CCCM) services and for proposing adoption of a number of provisions included in our multispecialty proposal and the CPT 2014 guidelines. That said, in reviewing the rule, we have a number of concerns with the CMS proposal on CCCM, which we discuss in detail below. We hope to work with CMS to address these concerns which include adequate definition of the services, the patient population that should be eligible to receive CCCM, the requirements for practice eligibility, and how to best minimize barriers to furnishing these services.

As a threshold matter, we believe these services should not only recognize and reward those practices who are already performing CCCM but also should serve as a bridge to stimulate practice transformation as healthcare delivery changes to more integrated systems of care. While implementing these codes may implicate a number of complex payment policy issues, all of us share the goal of improving care by recognizing and making appropriate payment for these important non face-to-face services and we appreciate the support of CMS in this process.

#### **RECOMMENDATIONS**

- 1. CMS should not finalize or implement the proposed G codes and instead recognize and implement the two existing non face-to-face CPT codes.**
- 2. CMS should recognize the CPT descriptors and guidelines for CCCM services. The undersigned intend to propose changes to the existing CPT guidelines to address some of the issues raised by CMS in the proposed rule. For example, we will propose increasing the required clinical staff time for the base CCCM code to 60 minutes.**
- 3. CMS should include in the November 2013 Final Rule clear direction for what type of coding will be required to report CCCM services. Specifically CMS should state whether it will accept the base, add-on structure that is currently in CPT and, if so whether any additional codes need to be created, and, if not, what codes CMS wishes CPT to create (e.g., initial and subsequent)**

4. **CMS should include in the November 2013 final rule a set of coding guidelines that could be proposed to CPT for inclusion in CPT 2015, if necessary, so that CPT can make any revisions within the 2015 cycle.**
5. **CMS should not finalize its beneficiary protection proposals and instead finalize the multispecialty proposal detailed below.**
6. **CMS should propose alternative pathways for practices to use in order to be eligible to report and be reimbursed for CCCM services. Specifically, CMS could develop its own standards and methods of satisfying them, in addition to allowing recognition/accreditation by external organizations.**
7. **CMS should not establish any requirement for advanced practice nurses or physician assistants to be employed by practices eligible to report CCCM services.**
8. **CMS should allow independent contractors and Community Health Teams to be integrated into practices and should not require all clinical staff to be full-time W-2 employees of the practice.**
9. **CMS should not move forward with the proposed EHR requirement, or at a minimum create exceptions for on-call physicians from different practices without 24/7 access to the practices EHR.**

## **Discussion**

The CMS proposal to establish G codes for CCCM services is problematic. As proposed, the type of CCCM services and eligible patient population would be much different from the multispecialty proposal. In our view CCCM services are intense services delivered over a short (30 day) period of time to patients who are unstable and at great risk for hospitalization during that period of time.

The intent of the undersigned and the CPT codes is to recognize the need for intensive CCCM services provided to patients during the 30 day period immediately after a care plan is established or significantly revised due to the severity and instability of the patient's medical problems. We are attaching to this letter our proposal and incorporate it by reference into this comment letter.

The patients described in the proposal have an immediate need for intensive CCCM services delivered by clinical staff under the supervision of a physician. CCCM services as conceived in our proposal typically are required for only 30 days. The CPT codes and RUC valuation reflect the services described in CPT. The vignette which reflects the typical non face-to-face CCCM service, upon which the CPT code was valued is:

An 83-year-old woman with congestive heart failure and early cognitive dysfunction, who has been hospitalized twice in the prior 12 months, is becoming increasingly confused and refuses an office visit. She has a certified nursing assistant supervised by a home care agency, participates in a remote weight and vital signs monitoring program and sees a cardiologist and neurologist.

We agree with CMS that the CCCM services described in CPT and the RUC vignette would typically result in 60 minutes of clinical staff time in a one month period, as evidenced by the AMA RUC survey. We are hopeful that CMS agrees that the above vignette describes the CCCM patient and we request that CMS

confirm in the final rule its agreement that the CCCM services described in the proposed rule are appropriately described by the vignette and the calendar month CPT codes for CCCM services, assuming that the code is revised to describe “CCCM” services and a minimum of 60 minutes of clinical staff time. If CMS does not agree such is the case, we request that CMS state why it disagrees and to propose alternative language. In the proposed rule, CMS would only require 60 minutes of clinical staff time to be spent over 90 days. This is an average of twenty minutes per month. This requirement would be fulfilled with only one five minute phone call per week to a beneficiary with two or more serious diseases. Even more importantly, the CMS proposal does not allow higher reimbursement for CCCM provided to patients who are very ill and require well over 60 minutes of staff time spent on CCCM in a calendar month, let alone 90 days. This would mean that practices would be dramatically underpaid for such care. This issue could be addressed by implementing an add-on CCCM code - like the one already in CPT. Put another way, smaller amounts of CCCM furnished over a long time period resulting in the same total minutes are not clinically equivalent to greater amounts of CCCM furnished in a shorter time period because the patient population receiving the former is much different (less sick) than the patient population receiving the latter. In other words, we think the CMS proposal will make a much larger patient population eligible for CCCM services than was intended by CPT.

We also note that our proposal envisions that patients would likely receive CCCM services three or four times per year and, rarely, up to six times per year because even the very ill patients described in our proposal are not so unstable and changing as to require CCCM services for more than three or four calendar months in a year. Under the CMS proposal it is very likely that practices will be reporting (and getting reimbursed) CCCM services all year because if a patient requires CCCM for one month out of every three, the 90 day code would be reported every three months. The calendar month CPT code was developed by experts in this field who have a great deal of experience caring for these patients and we believe it reflects the actual care being delivered.

We also note that, a 90 day period creates a long time duration between performing services and reporting them. A 90 day requirement increases administrative burden and makes it less likely the services will be reported correctly. This issue has already occurred with Transitional Care Management (TCM). CPT elected to use calendar month as the reporting interval so as to simplify reporting. CMS has determined that reporting of TCM services cannot be done until the beneficiary has survived the 30 days. Patients receiving CCCM are complex and have a significant probability of death over a 90 day period so there is a greater potential for non-payment of services performed in the 90 day model as compared to the calendar month model.

CMS did not propose an add-on code. This means that payment will be the same no matter how much CCCM is delivered beyond the 60 minute time threshold for clinical staff. This does not allow practices to be reimbursed for the sickest patients - the ones that most need CCCM and will most likely benefit from CCCM. Not including an “add-on” code for practices to report may result in defeating the entire purpose of the CCCM codes.

We are concerned that the larger, less homogeneous patient population described by the G codes with the open ended time interval after 60 minutes will make valuation very difficult. The typical patient is likely to be less complex and we are concerned that the RVUs that will be assigned to the proposed 90 day code may be the same as or similar to the RVUs already assigned to the current non face-to-face calendar month base code (99487) and, practices simply will not be able to afford to provide CCCM if there is no ability to report all the time spent furnishing CCCM services to their patients who truly need the service. More specifically, we are worried that CMS will value its proposed 90 day code based on 60 minutes of staff time because valuing it any higher could result in overpayments for some patients.

However, under the CMS proposal, such a valuation would, as described, dramatically underpay for care delivered to those that need it most and are the most likely to benefit.

We also disagree with the proposal for an “initial” and a “subsequent” CCCM code. The proposal assumes that the “initial” CCCM services are different from the “subsequent” services. This is not necessarily true. It also creates a need to define initial and subsequent which creates greater coding complexity. The services are the same, especially when there is an allowance for an add-on code because CPT 2014 requires significant change in the care plan to report CCCM.

However, we do agree with the CMS proposal for requiring 60 minutes of clinical staff time for the base code and will propose that to CPT. We also will propose that CPT delete the current CCCM code that includes a face-to-face visit because we agree with the CMS proposal to continue to make separate payment for face-to-face visits during periods when CCCM is reported. Lastly, we agree with changing the description of the services from complex chronic care coordination to complex chronic care management and will propose such a change to CPT. In our view “management” includes coordination of care. Therefore, we would like CMS to clarify in the November 2013 Final Rule that the practice reporting CCCM does not have to perform all care management itself and that other practices or practitioners can perform some management in coordination with the reporting practice.

Another reason to adopt CPT codes is to promote uniform coding among payers and programs. This is important administrative simplification and may promote all payers contributing to practice transformation. G codes are Medicare specific and it is important that pediatric patients with chronic complex conditions are able to access such services.

#### **Beneficiary Protection Requirements Could Limit Access to CCCM Services - Request Clarification**

The current CCCM proposal includes a number of notice and informed consent requirements that providers must satisfy before billing Medicare for these services. CMS has proposed that beneficiaries will have to give informed consent both prior to the initiation of CCCM services and at least every 12 months thereafter. Beneficiaries will also have an opportunity to refuse CCCM services.

This latter proposal is very concerning to us. Except in cases where the beneficiary has refused consent for the service, providers will also have to notify beneficiaries that a claim for CCCM services is being submitted to Medicare before actually submitting the claim. In addition, certain requirements as proposed appear too onerous for many providers, which may, in turn, limit beneficiary access to these important services. **Accordingly, we ask that CMS not finalize its beneficiary protection proposal as currently contemplated and instead finalize the multispecialty proposal detailed below, which provides clarifications to the CMS proposal.**

Because CCCM services will not always be provided face-to-face, we agree that there must be some limits on the situations in which the new codes can be used in order to protect beneficiaries and also to deter program fraud and abuse. We also agree that beneficiaries should be made aware they will, or are, receiving CCCM services. The requirement for beneficiaries to agree to CCCM services needs to be clarified otherwise it has the potential to interfere with many physician-patient relationships. For example, even if a patient who needs CCCM services does not want to pay for such services, his or her treating physician will, in most cases, still have an ethical obligation to provide the necessary coordination of care but will not be able to seek reimbursement for those efforts. In short, we don't think beneficiaries should be required to provide express informed consent for CCCM services. When patients are seen by physicians at the time of an office visit, they are assumed to have given implied

consent to be seen and treated. While a patient may refuse to have services such as blood tests or x-rays, they are not usually asked to provide explicit consent for a service unless the service is high risk. In general, for low risk services, physicians are expected to inform patients as to what services are being provided and why they are being provided. Beneficiaries are assumed to have given consent if they do not object. Beneficiaries should be assumed to have given consent for CCCM services after the service has been explained to them unless they object - just as they would for any other low risk service. In such cases, the services, if performed, should be billable and the physicians should be allowed to waive the coinsurance amount. Requiring express informed consent for CCCM services would be time consuming, burdensome and would be a departure from standard medical practice.

Accordingly, we believe that practices who meet the requirements for reporting CCCM services, and who intend to report CCCM services to Medicare, should take the following actions to protect beneficiaries and maintain program integrity:

- At the time a care plan is created, a practice should notify the beneficiary for whom the plan is being created and/or their caregiver that the practice provides non face-to-face CCCM services and that these services may be billed to Medicare from time-to-time. This notification should include a description of the services and how the practice determines whether such services are medically necessary. This information can be provided orally or via a fact sheet; however, the notification must be documented in the care plan. This notification should be updated periodically, but no less frequently than once a year. The initial and subsequent beneficiary notifications, as well as any relevant discussion, should be documented in the medical record and available upon request. Specifically, it should be documented as part of the care plan and any revision or refinement to that plan.
- For any period where a practice determines that it has met the requirements to report CCCM services, the practice should notify the beneficiary and/or their caregiver that a bill will be submitted to Medicare for CCCM services. The notice should remind the beneficiary that he or she has been receiving CCCM services during that calendar month, clarify the reason(s) for providing the services, and thoroughly describe the services that were provided. The practice should have an established process for beneficiaries to ask questions about the CCCM services that were provided and to dispute whether those services were, in fact, provided. The notice may be delivered in person (e.g., at the time of an office visit) or sent by mail, email or facsimile, but must be sent before the practice submits the claim for CCCM and must be given each month for which a CCCM service is billed. The notice should be documented in the care plan as should any dispute or other relevant discussion (including a notation that “the beneficiary was notified and did not dispute that CCCM services were furnished” when appropriate). After such notification, the practice should submit a claim for CCCM services to Medicare. All notices described may be made orally or in writing (e.g., email, letter, fax) and documented in the medical record.

### **Commitment to Practice Transformation**

In the proposed rule, CMS recognizes that not all practices that care for beneficiaries with complex chronic conditions currently have the capability to provide CCCM services without making additional investments in technology, staff, training, and other systems improvements. As such, we appreciate the agency’s intention to develop standards for furnishing CCCM services in order to ensure that the physicians who bill for these services have the capability to provide them. However, we would caution

the agency against developing standards that are too restrictive or that may ultimately prevent practices that are otherwise qualified to provide CCCM services from participating in this initiative.

Although the undersigned groups share the agency's commitment to help practices make the changes that will be necessary to implement innovative delivery models, we encourage CMS to provide additional clarification about the policy goals for the proposed CCCM codes in this year's final rule or in next year's proposed rulemaking. Specifically, we would appreciate guidance on whether the new codes are intended to only reimburse those practices that already have CCCM capability or whether the codes are part of an effort to provide interested practices with the possibility of obtaining reimbursement as they go about establishing the necessary infrastructure and as they gain experience with CCCM services. Our strong preference is for the latter goal - especially as it helps ease the transition to new payment models. At the very least, the agency's final proposal for practice standards should not be so narrow as to limit beneficiary access to these critical services by allowing only a few large highly integrated practices to bill for CCCM services.

To that end, we believe that all practices that wish to be eligible to report CCCM services must have the following capabilities:

- Provide 24/7 access to care providers or clinical staff (in person, by phone or electronically);
- Use a practice specific standardized methodology to identify patients who meet the CMS requirements for CCCM services (i.e., risk-stratify patients);
- Have an internal care coordination process/function whereby a patient identified as meeting the requirements for CCCM services starts receiving those services immediately upon referral;
- Include a practice-specific care plan using a standardized data collection tool, form and format within the medical record that is separate from the progress notes; and
- Be able to engage and educate patients and caregivers as well as coordinate care across the medical neighborhood, as appropriate for each patient.

We appreciate the agency's inclusion of these principles in the list of practice standards on which it is seeking comments and feedback. However, we also note that several of the potential practice standards listed in the proposed rule have the potential to limit the number of otherwise qualified practices that are able to provide CCCM services.

CMS is asking for comments on whether a practice must utilize an electronic health record that meets the most recent regulatory standards for meaningful use in order to provide all members of a patient's care team with 24/7 access to the patient's records. While we certainly see the value in leveraging a practice's EHR capability, the potential practice standard under discussion appears to suggest that all of the EHRs used by the various providers who are involved in a beneficiary's care must be interoperable. If so, then we are concerned that this standard could limit access to CCCM services because complete interoperability is not yet attainable for many physicians. Furthermore, we are concerned about the proposal to require 24/7 access to the practices EHR. In cases where the on-call physician is from a different practice or does not have access to the EHR for other reasons, the practice would not be able to report CCCM services. We request that CMS not move forward with this requirement or, if it does, that it create exceptions to the requirement for situations like the above.

CMS has also stated that it may require practices providing CCCM services to employ an advanced practice registered nurse (APRN) or physician assistant (PA) whose written job description indicates that

their job roles include and are appropriately scaled to meet the needs for beneficiaries receiving these services in the practice. We appreciate the value of teams, but do not agree that APRNs or PAs must be employed by a practice in order for the practice to be qualified to perform and report CCCM services. We are not aware of any published data on CCCM services supporting such a requirement. In fact, implementing such a proposal would inappropriately disqualify a number of practices that have achieved level 3 NCQA certification, or comparable certification from other accreditation entities, from billing for CCCM because they do not employ APRNs or PAs.

Instead, we recommend that the agency provide greater flexibility for practices to demonstrate that they have the structural capabilities, personnel, and systems to coordinate care effectively. For example, CCCM services are usually performed by registered nurses and other qualified health care professionals under physician supervision. Practices should be able to perform and report CCCM services if those health professionals are part of the CCCM team. Given that CMS would allow APRNs to perform CCCM services without hiring a physician or without the involvement of a physician, we find it difficult to understand why CMS would require a physician to hire an APRN in order to report the same services.

CMS also is considering whether to require practices to be recognized as a patient-centered medical home (PCMH) by one of the national accrediting bodies (e.g., National Committee for Quality Assurance; Accreditation Association for Ambulatory Health Care; The Joint Commission; URAC) in order to provide and report CCCM services. We disagree with such a requirement. In general, medical societies have shied away from proposals that would require medical homes or patient-centered practices to obtain accreditation/recognition by external entities. That said, we have no problem with CMS making accreditation one option as a path to reporting CCCM services. If CMS wants to propose accreditation as one path to reporting CCCM services then it is important for CMS to work with the medical community to establish an alternative path such as attesting to meeting specified regulatory criteria (e.g., having an EHR, a standardized methodology for identifying patients who may benefit from CCCM). Such a pathway should not be burdensome but should be rigorous enough that practices who can make such an attestation also would likely meet the requirements for being an accredited medical home. Two specific concerns with requiring accreditation are (1) that many current accreditation/recognition programs are limited to primary care practices whereas CCCM should be a defined service by a qualified practice to an appropriate beneficiary without restriction to specific specialties so that the beneficiary choice is preserved, and (2) that accreditation is very expensive and requires frequent recertification. Many practices cannot afford accreditation and the undersigned are not willing to agree to a process that would require their members to pay for accreditation in order to report CCCM services to the fee-for-service Medicare program.

### **Expand Ability to Provide “Incident To” CCCM Services**

We strongly believe that CCCM services are and will be performed pursuant to a care plan ordered by a treating physician who is regularly involved in implementing and updating the plan and is kept informed as to the patient’s condition. In order to provide 24/7 access, however, CCCM services will necessarily be provided while the physician is not in the office (or after office hours) by clinical staff operating “incident to” the physician’s services. As such, we appreciate the agency’s recognition that CCCM services provided by clinical staff outside of a practice’s normal business hours may properly be provided under the general supervision of the treating physician and still be counted towards the one hour requirement as “incident to” services. We believe, however, that limiting the clinical personnel who can provide “incident to” CCCM services to individuals who are “directly employed by the physician” will unnecessarily restrict beneficiary access to these services. Although we recognize the

difficulties in making exceptions to the agency's "incident to" policies, we recommend that CMS allow otherwise qualified practices to provide "incident to" CCCM services through independent contractors. Allowing independent contractors to perform some CCCM services is not the same as providing them "under arrangement" because the practice directly supervises the contracted individual performing the service. Requiring a practice to have all possible CCCM services performed by W-2 employees could undermine access to CCCM as most practices will never have the capability to perform all CCCM services themselves (e.g., social work, community support).

In the proposed rule, the agency notes that it currently allows practitioners to furnish "incident to" services to homebound patients in medically underserved areas using personnel who are "employed by the same entity, or an independent contractor of" the practitioner. We would encourage CMS to adopt a similar approach for "incident to" CCCM services. If a practice incurs the expense of independent contracting to ensure 24/7 access to services, then we see no reason why that practice should not then be able to apply the time that the independent contractor spends providing CCCM services towards determining its eligibility to bill for such services.

#### **CMS Should Not Tie CCCM Services to the Annual Wellness Visit (AWV)**

We support that CCCM services be provided by a practice that the beneficiary views as their primary source of care and by a practice that "provides or oversees the management and/or coordination of services, as needed, for all medical conditions, psychosocial needs, and activities of daily living" (CPT Guidelines). We appreciate that the AWV provider may serve as a method of patient attribution to practices for CMS. However, the AWV has many characteristics that allow it to be performed by practices that are not the beneficiary's chosen primary source of care for their CCCM needs, or even a primary care practice. Additionally, the prevention focus of the AWV is inconsistent with the care needs of the typical CCCM patient and performing an AWV may not be appropriate. Similarly, the patient condition at the time the AWV was furnished may have substantially changed and it is possible CCCM services may need to commence before being able to perform the AWV. We believe that the requirement to perform or obtain the AWV serves as an administrative barrier to the performance of CCCM and could actually serve to require performance of services that are not medically necessary for the sole purpose of being able to perform and report the medically necessary CCCM services. There is not a good clinical rationale to require the AWV given the required contents of CCCM.

However, we do support a requirement that CCCM services only be reported by physicians who have had a face-to-face visit with the patient within 90 days of a calendar month reporting period of CCCM services. The visit could be an AWV, but it does not have to be an AWV. It would provide the necessary assurance that the clinicians overseeing the CCCM services have an accurate and up to date knowledge of the patient condition. This is similar to the approach taken by CMS with respect to certification of home care. This approach would allow CCCM to be initiated as long as a face-to-face service for the relevant condition(s) is timely and up to date.

The Guidelines in CPT 2014 essentially address all the key relevant components of the AWV, though these could be made more explicit in some cases, if necessary. Therefore, we believe a tie to the AWV creates an administrative burden, but does not improve assessments and care. We provide examples in the table below:

Element	AWV	CPT 2014
<b>HRA</b>	<p>Collects self-reported information known to the beneficiary;            Can be administered by the beneficiary or health professional before, or as part of, the AWV encounter;            Takes no more than 20 minutes to complete; and            At a minimum, addresses:            Demographic data, Self-assessment of health status, Psychosocial risks, Behavioral risks, Activities of daily living (ADLs), and Instrumental ADLs.</p>	<p>Patients who require complex chronic care coordination services may be identified by practice specific or other published algorithms that recognize multiple illnesses, multiple medication use, inability to perform activities of daily living, requirement for a caregiver and/or repeat admissions or emergency department visits....            A care plan is based on a physical, mental, cognitive, social, functional and environmental (re)assessment and an inventory of resources and supports.</p>
<b>Written Screening Schedule</b>	<p>Establishment of a written screening schedule for the beneficiary, such as a checklist for the next 5 – 10 years, as appropriate</p>	<p>N/A as would rarely be appropriate for the CCCM patient.</p>
<b>Functional Ability and Level of Safety</b>	<p>Use direct observation of the beneficiary or any appropriate screening questions or a screening questionnaire, which the health professional may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations to assess, at a minimum, the following topics: Hearing impairment, Ability to successfully perform ADLs, Fall risk, and Home safety.</p>	<p>A care plan is based on a physical, mental, cognitive, social, functional and environmental (re)assessment and an inventory of resources and supports. It is a comprehensive plan of care for all health problems. It 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 practice will be directed/coordinated, identify the individuals responsible for each intervention, requirements for periodic review and, when applicable, revision, of the care plan.</p> <p><b><i>Safety could be added as an explicit element, though is implicit.</i></b></p>

Each of the undersigned organizations discuss these recommendations and other related policy issues in much greater detail in their individual comment letters to this proposed rule. Again, we thank CMS for the opportunity to comment on this hugely important matter.

Sincerely,

**AMDA - Dedicated to Long-Term Care Medicine**  
**American Academy of Child and Adolescent Psychiatry**  
**American Academy of Home Care Physicians**  
**American Academy of Hospice and Palliative Medicine**  
**American Academy of Neurology**  
**American Academy of Pediatrics**  
**American College of Chest Physicians**  
**American College of Physicians**  
**American Gastroenterological Association**  
**American Geriatrics Society**  
**American Psychiatric Association**  
**American Society for Blood and Marrow Transplantation**  
**American Society of Gastrointestinal Endoscopy**  
**American Thoracic Society**