September 2, 2014

Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1612-P
Mail Stop C4-26-05
7500 Security Boulevard,
Baltimore, Maryland 21244-1850.

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015 (CMS–1612–P)

Dear Administrator Tavenner:

The undersigned medical specialty societies are writing to comment on the Chronic Care Management (CCM) proposals made in the Physician Fee Schedule (PFS) Proposed Rule for Calendar Year (CY) 2015 (CMS–1612–P). We have been working with the Centers for Medicare & Medicaid Services (CMS) for the past three years on implementing CCM in the Medicare fee-for-service program. We want to thank CMS for the time and effort they have spent on this issue. We are particularly pleased that CMS has recognized the importance of non-face-to-face team based patient centric care and 24 hours, 7 days a week access in achieving the delivery of high quality health care to Medicare beneficiaries. Establishing payment for transitions of care management services was a big first step and establishing separate payment for chronic care management will be an even bigger step.

All Medicare beneficiaries with two or more chronic diseases can benefit from proactive team-based patient-centric care coordination. However, the type and intensity of services, physician and clinical staff time and other resources necessary to provide value vary significantly by the complexity of the patient. Therefore, just as it would be impractical to describe all spine surgeries (minimally invasive to multi-level with hardware) with a single code, it is likewise impractical to expect a single code to describe the heterogeneity of the physician work and clinical staff effort required to provide team based chronic care management across such a wide range in this family of “cognitive procedures.”

Over the years, our recommendations have always focused on asking CMS to establish payment for chronic care management services on one end of the spectrum of team based care coordination, those targeted to the sickest Medicare patients as we believe such a payment will
be a major step forward in achieving our shared goals. We note that this is also the patient population which is the most costly to Medicare on a per capita basis. We call this service “complex chronic care management (CCCM).”

CCCM has been demonstrated in numerous clinical trials to improve the quality of care in the most complex patient population. It has not been studied in patients who can achieve their treatment goals without individualized care plans or in patients who can be treated according to published guidelines (i.e., using the principles of disease management). CCCM is a resource intensive service that requires a team of trained health care professionals acting together to implement individualized care plans for patients whose clinical condition makes them at high risk for hospitalization or visits to the emergency department. Importantly, many of these patients should not be treated using published guidelines and standard care. Guideline based care often involves affirmative interventions such as adding medications, performing diagnostic tests, undergoing surgery or being hospitalized. However, the patient population our organizations have been discussing with CMS will not benefit from and may actually be harmed by guideline based care (e.g., an 85 year old with dementia, diabetes and functional impairment who is on multiple medications and requires a caregiver or for a disabled dual eligible 35 year old schizophrenic with diabetes). On the other hand, guideline based care, which lies at the other end of the spectrum of team based coordinated care, is appropriate for the majority of Medicare beneficiaries with two or more chronic conditions (e.g., a 65 year old with diabetes, high cholesterol and hypertension who is trying to avoid vascular complications).

Therefore, our organizations were very pleased when CMS proposed and finalized a G code last year for chronic care management along with a scope of services that was appropriate for complex patients. However, we were surprised at, and disagree with, the proposed payment amount of $43.67 for GXXX1 in this year’s proposed rule. The proposed amount is insufficient to provide the scope of services CMS is requiring for billing the code. Put another way, the proposed payment is insufficient to provide CCCM to the complex patients we have been describing. The services required to deliver CCCM demand significant clinical staff time and physician supervision. The clinicians who perform these services say it takes a minimum of 60 minutes of clinical staff time per month to deliver CCCM. This number was recently confirmed by a RUC survey (see below).

It appears that the explanation for this disconnect is that CMS intends the patient population eligible for this service to be those whose care needs lie at the opposite end of the chronic care continuum from the patients who need CCCM. That is - patients who can be managed according to disease specific clinical guidelines. This intended patient population is much larger than the population of patients who require CCCM. While we are uncertain as to
just how large this population is, it seems as if many patients with two or more chronic conditions will be eligible. ¹

This raises a critical issue. Most patients in the CMS intended population do not need to be managed with a comprehensive care plan or special management of care transitions because they are cognitively intact and capable of managing their own medications and interactions with the health care system. Our organizations are worried that the physicians billing for this service will not be able to demonstrate that they performed the full scope of required services. We are also worried that, even though CMS intends for the eligible patient population to be large, because CMS has not defined what it means by “significant risk” that Medicare and other compliance auditors could take the position that patients for whom the service was billed were not “at significant risk” and request a refund.

We are particularly worried because even though the G code language was copied from language in the Current Procedural Terminology (CPT) book, the complete discussion in CY 2015 CPT is much more extensive and describes and differentiates between two different types of chronic care management. For example, even though there is no description of a typical patient, CPT notes that patients requiring CCCM are a subgroup of patients with multiple illnesses and are identified by algorithms on the basis of having been hospitalized multiple

¹ For example, millions of Medicare beneficiaries have two or more of the following conditions and many of them, arguably, are at significant risk of death, acute exacerbation/decompensation, or functional decline:

- Heart failure
- Poorly controlled diabetes mellitus
- Neurocognitive disorders (e.g., Alzheimer’s disease)
- Mental illness (e.g., major depression) and substance use disorder
- Symptomatic coronary artery disease
- Symptomatic peripheral arterial disease
- Chronic obstructive pulmonary disease (emphysema)
- Stroke with sequelae that place the patient at risk for, among other things, falling and fracture and aspiration pneumonia
- Inflammatory bowel disease
- Chronic liver disease
- Bone marrow disorders such as leukemia and aplastic anemia
- Uncontrolled hypertension
times, having functional impairment, requiring a caregiver to adhere to a treatment plan, etc. In CPT this group of patients is differentiated from other patients who require much more basic, or standard, chronic care management. It appears that even though we thought the G code language was intended to describe complex chronic care management - it is now being used to describe patients who do not need complex chronic care management. We worry that this may be very confusing to physicians who are trying to code this service correctly.

We understand that technically the scope of services and G code descriptor are not open for comment and that the only topics open for comment are: the proposed valuation of the G code, the proposed revisions to the ‘incident to’ rules, the proposal to require use of a certified electronic health record and the proposal to only allow professionals participating in two specified demonstration projects to bill the G code on their patients who are not enrolled in those demonstrations. This letter contains our comments on all four of these proposals. That said, we believe that to make our concerns about the published scope of services and proposed payment amount as clear as possible, we spend significant time discussing and differentiating two types of chronic care management and what the implications are for the G code descriptor, the published scope of services and the proposed payment amount. In this regard, we ask that CMS take the following into account as it determines whether to finalize its proposals:

It is essential that CMS recognize the differences between complex chronic care management (CCCM) which lies at one end of the spectrum of chronic care management and the much more basic, guideline based chronic care management which is also known in the medical community as disease management. For purposes of this letter we refer to this more basic form of chronic care management as “standard” chronic care management or SCCM. These are two distinct services that are targeted to two completely different patient populations with very different needs. There is no ‘typical’ patient characterization which describes both groups simultaneously. Most patients with chronic disease can be managed with SCCM. This means that they can be managed using standard disease specific practices such as office visits at pre-specified intervals, regular pre-specified diagnostic and laboratory testing, standard medication use and standard preventive care and age/gender appropriate immunizations. CCCM, on the other hand, is required for patients who cannot or should not be treated using standardized guidelines. Examples include patients with cognitive impairment and multiple chronic diseases being managed by multiple providers on medications with a high risk of adverse events who require a caregiver to adhere to the treatment plan and are at high risk for hospitalization.

Below is a more detailed description of how typical SCCM and CCCM services differ in terms of their scope, intensity, and intended patient populations.
SCCM:

Typical Scope of Services:

- Minimum 20 minutes of clinical staff time per month
- Intensity, stress levels are lower
- 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.
- Teaching (e.g. diet, exercise) and reminders to obtain disease appropriate care (e.g., regular eye examinations, foot care, blood tests)
- Reminders to obtain evidence-based, age and gender appropriate, recommended immunizations and preventive services
- Patient screening (including screening for psychiatric conditions and substance use disorders), referral and management centered around accepted, published guidelines
- Coordination with other health professionals and community services as needed
- Use of evidence based medicine, disease registries, published practice guidelines to achieve treatment goals is appropriate
- Communication centered around compliance with protocols, whether guidelines and treatment goals are being met
- The comprehensive care plan is limited to following published practice and preventive care guidelines

Patient Population:

- Two or more chronic diseases expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of increased morbidity, complications, or functional decline
- Minimal or no functional impairment
- Does not require a caregiver
- Current condition places patient at low risk of needing hospitalization or visit to the emergency department
- Patients who are capable of learning how to, and perform, self-management of their disease
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CCCM:

Typical Scope of Services:

- Requires a minimum of 60 minutes of clinical staff time per month
- Intensity and stress levels are much higher
- 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 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 telephone access as well as secure messaging, internet or other asynchronous non face-to-face consultation methods.

Patient Population:

- Patient has two or more diseases and whose current condition places the patient at a significant risk of death, deterioration or functional decline such that hospitalization or visit to the emergency department is likely
- Patients medical condition is of such complexity that the patient is not suitable for typical disease-defined guideline management and an individualized treatment plan is required
Individualized care planning typically requires interdisciplinary communication centered around the patient’s changing clinical condition.

Patients requiring complex chronic care management will typically have two or more of the following:

- Cognitive impairment
- Mental illness
- Substance use disorder
- Functional impairment of activities of daily living and/or instrumental activities of daily living
- Low health literacy/cultural barriers
- Caregiver required in order to achieve treatment goals

We believe that the differences in the scope of services and patient populations described above clearly demonstrate that these are two distinct services with completely different types of physician work and clinical staff requirements. In our view, the CMS proposal fails to recognize that the type and intensity of physician supervision and the type and intensity of clinical staff resources required to perform SCCM are entirely different from those required to perform SCCM. The proposed physician work RVU of 0.61 and clinical staff time of 20 minutes do not reflect the physician work and clinical staff time required for SCCM, they are more appropriate for SCCM. The proposal of 0.61 work RVUs is based on the non-face-to-face work of 99214, the lower level transition of care management (TCM) code. CMS assumed that the face-to-face visit included in 99495 was a 99214 with a work RVU of 1.5. CMS then subtracted 1.5 from the total work RVU for 99495 of 2.11. Our organizations believe that a more appropriate work RVU for CCCM would be calculated based on the non-face-to-face physician work of 99496, the high level transition of care management (TCM) code. The patient acuity for 99495 and the physician work requirements and intensity are lower for 99495 than for 99496. The CMS proposed work RVU may be appropriate for an SCCM code - but it is not for a CCCM code. The patient acuity of 99496 is more similar to that of patients who require CCCM as is the level of medical decision making. 99496 also includes a face-to-face visit which is most likely to be either 99214 or 99215 (work RVU of 2.11). Subtracting the work RVU for 99214 or 99215 from that of 99496 (3.05) results in a non-face-to-face work RVU of 1.55 in the case of 99214 or 0.94 in the case of 99215. These numbers are consistent with the RUC recommended work RVU of 1.0 for the CPT CCCM code 99487 which was based on a multi-specialty survey of 147 physicians.

As stated above, review of the clinical condition of the patients who receive these services makes it clear that there is no single “typical patient” that could describe both of these services. SCCM and CCCM each have their own typical patients. These two services cannot be described by a single billing code just as open surgical procedures and minimally invasive procedures have different codes.
Therefore, our recommendation to CMS, as described below, include establishing two billing codes for chronic care management in CY 2015 - one for SCCM and one for CCCM.

With respect to the other proposals we offer the following comments:

**Requirement to Utilize a Certified Electronic Health Record**

We disagree with the proposal to require practices to utilize an electronic health record (EHR) that has been certified by a certifying body authorized by the National Coordinator for Health Information Technology in order to bill GXXX1. This requirement means that many physicians will need to acquire a completely new EHR solely for the purpose of billing CCM. Most physicians do not have certified EHRs, and even fewer have EHRs that are certified for meaningful use, stage II. Additionally, physicians who work in facility settings don’t have a choice of EHR and if the facility’s EHR is not certified then they would be unable to bill GXXX1. Moreover, this requirement will not add any value to the service because most EHRs - physician and facility - are not interoperable. Although we agree that interoperability is important and that it is laudable to promote interoperability - the fact is that it doesn’t exist in 2014. Requiring a certified EHR will mean that CCM will not be provided to the beneficiaries who will benefit from it. We recommend that CMS revisit this issue in 3 or 4 years hence when it is anticipated that interoperability will be more widespread and purchasing a certified EHR would add value to the service.

**Overlap with the Care Coordination Payment in Two Demonstrations**

CMS proposes to not make a chronic care management payment to practices in the Multi-payer Advanced Primary Care Practice Demonstration and the Comprehensive Primary Care Initiatives for patients attributed to participating practices. We have two comments:

1. Any payment for any chronic care management code in the fee-for-service program should not be constrained by the payment amount in a demonstration project. The two payments are completely unrelated and are made for different purposes to very different physician practices. Demonstrations are intended to study certain types of care delivery and have specific financial incentives (e.g., participation in shared savings). Therefore, any comparison between a fee-for-service payment and a demonstration payment is inappropriate.

2. We do not believe it is possible to know with certainty whether there is overlap between a fee-for-service chronic care management payment and a payment for care coordination in a demonstration. Demonstration project payments may be risk adjusted and/or negotiated and are based on other potential revenue generated by the participating practices. However, it is our understanding that many demonstrations allow participating practices to bill, and be paid for, services under the Medicare fee-for-service program. We believe that if other
services may be billed, then chronic care management services should be payable as well. Why would Medicare pay for office visits, surgeries etc. but not chronic care management? That said, because there could be overlap, we recommend that CMS pay to participating practices for patients attributed to them for purposes of the demonstration, an amount equal to the difference between the fee-for-service chronic care management payment and the demonstration payment for that patient. If the fee-for-service payment is less than the demonstration payment, then the practice would receive only the full demonstration payment.

Proposal to Revise the ‘Incident To’ Rules for Chronic Care Management

We support the CMS proposal to remove the requirement that clinical staff performing CCM activities must be direct employees of the physician practice. We also support the proposal to allow clinical staff to perform CCM activities during normal business hours even when the physician is not present in the office. We appreciate that CMS understands that CCM activities are performed 24/7 and that it is inherent to the service that the physician has trained staff performing CCM and that there are regular interactions between clinical staff and physicians. We thank CMS for these proposals.

Recommendations:

A. We request that CMS adopt and finalize two codes in this year’s final rule - one for SCCM services and one for CCCM services:

1. Implement Complex Chronic Care Management (CCCM) as follows:
   - Make CPT code 99487, Complex chronic care coordination services; first hour of clinical staff time directed by a physician or other qualified health care professional with no face-to-face visit, per calendar month, active and payable for CY 2015
   - Use the RUC recommended inputs for 99487 to establish payment for 99487
   - Define the required scope of services for billing 99487 as those services listed above for CCCM services
   - Define the patient population eligible for complex chronic care coordination services under 99487 as those listed above for CCCM services

2. Implement Standard Chronic Care Management (SCCM) as follows:
   - Finalize GXXX1 with the following changes to the proposed descriptor. These changes will differentiate the G code from 99487 and changing the period to calendar month will make it easier to report:
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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 increased morbidity, complications, death, acute exacerbation/decompensation, or functional decline, 20 minutes or more of clinical staff time; per 30 days calendar month

- Establish a payment amount for GXXX1 with the proposed work and practice expense inputs
- Define the scope of services required for billing GXXX1 as those listed above for SCCM services
- Define the patient population eligible for disease management services under GXXX1 as those listed above for SCCM services

We understand that technically the G code descriptor is not open for comments. However, we believe that our proposed changes are editorial and will clarify the code so as to minimize confusion and promote more accurate coding.

- Deletion of the words “significant” and “death, acute exacerbation/decompensation” will more accurately describe this population and better differentiate this patient population from the patient requiring SCCM services
- Addition of the words “increased morbidity, complications” will better describe the treatment goals of this patient population
- Change from “per 30 days” to “calendar month” is critically important as it will simplify record keeping and billing and is for administrative simplification. The “per 30 day” descriptor for TCM services makes sense because patients can be discharged from a facility on date that is well documented, easily available and auditable. Unfortunately, our members still have difficulty in successfully reporting TCM services. SCCM services are entirely different. The start date is likely to be different from the date on which the patient agrees to have care. It will also be very difficult to know when SCCM starts and where post face-to-face visit care ends. Lastly, there is likely to be a time period between SCCM services (e.g., SCCM services end on September 5th and resume on September 14th) that is highly variable. It will be highly problematic and burdensome for any practice to keep track of and document these dates. This will make audits virtually impossible to perform.

Our organizations would support an alternative to finalizing the G code. CMS could recognize the new CPT code 99490 for reporting SCCM services (instead of finalizing the G code) and establish a payment amount based on the proposed work and practice expense inputs for GXXX1.

B. Do not finalize the proposal to require a certified EHR in order to report and bill for CCM services and revisit this issue in 3-4 years when interoperability may be more widespread
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C. Do not constrain any fee-for-service chronic care management payment by the payment amount in a demonstration project

D. CMS should pay practices participating in a demonstration, for patients attributed to them for purposes of the demonstration, an amount equal to the difference between the fee-for-service chronic care management payment and the demonstration payment for that patient. If the fee-for-service payment is less than the demonstration payment, then the practice would receive only the full demonstration payment.

E. Finalize the proposal to allow clinical staff to perform “incident to” activities at any time including during normal business hours and to remove the requirement that clinical staff performing CCCM must be direct employees of the physician practice

Additional Discussion on Logical Outgrowth

We are including a brief discussion of the “logical outgrowth” requirements of the administrative procedure act because we believe that CMS is legally able to finalize all of our recommendations for coding and payment for SCCM and CCCM services.

We believe that our recommendations are a logical outgrowth of the proposed rule. From the perspective of the administrative procedures act, if a final rule resolves issues within the scope of the original proposal scheme and is a logical outgrowth of that proposal and the comments received during the rule-making process, a new period of notice and comment is not required. In this case, the disconnect between the proposed payment and required scope of services for GXXX1 and our recommendation to resolve that inconsistency by recognizing two codes to describe two different services is within the scope of CMS’s proposal for chronic care management and is a logical outgrowth of that proposal particularly in light of the ambiguity

2 See, American Trucking Assoc., Inc. v Fed. Motor Carrier Safety Admin., 2013 WL 3956992 at *7 (DC Cir Aug. 2, 2013) (finding that a final rule imposing a off-duty break of at least 30 minutes to short haul drivers was a logical outgrowth of the proposed rule, which would have require short-haul drivers to comply with a broader range of regulations which included off-duty breaks); In re Polar Bear Endangered Species Act Listing and Section 4(D) Rule Litigation - MDL No. 1993, Safari Club International, et al. v. Jewell, 720 F.3d 354, 363 (D.C. Cir. 2013) (finding that the plaintiffs should have anticipated the agency’s final course in light of the initial notice, rendering the final rule a logical outgrowth of its notice) (internal quotations omitted); United Steelworkers of America, etc. v Marshall, 647 F2d 1189 (D.C. Cir. 1980), cert. den. 453 US 913 (1981) (upholding a final workplace safety rule limiting employee exposure to airborne lead in concentrations greater than 50 micrograms per cubic meter and have different phase in periods for different industries, although OSHA had proposed to lower the permissible exposure level to 100 micrograms per cubic meter for all industries), See also, Spartan Radiocasting Co. v Federal Communications Comm’n., 619 F2d 314 (4th Cir. 1980) (holding that a NPRM must be sufficient to fairly apprise interested parties of the issue involved but need not specify every precise proposal that the agency may ultimately adopt as a rule).
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(and susceptibility to interpretation) of the descriptor of GXXX1 with respect to the eligible patient population and scope of services.

* * * * *

We greatly appreciate the opportunity to comment on this proposed rule. Please do not hesitate to contact us (Alanna Goldstein at agoldstein@americangeriatrics.org or 212-308-1414) if we can provide any additional information or assistance.

Sincerely,

American Academy of Home Care Medicine
American Academy of Hospice and Palliative Medicine
American Academy of Neurology
AMDA – The Society for Post-Acute and Long-Term Care Medicine
American Geriatrics Society
American Psychiatric Association
American Society for Blood and Marrow Transplantation
American Thoracic Society