SUBMITTED ELECTRONICALLY VIA

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Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1631-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 and Other Revisions to Part B for CY 2016 (CMS–1631–P)

Dear Mr. Slavitt:

The undersigned medical specialty societies [hereinafter, "Coalition"] appreciate the opportunity to provide comments on the Medicare Physician Fee Schedule ("MPFS") Proposed Rule for Calendar Year ("CY") 2016 (CMS–1631-P) [hereinafter, "Proposed Rule"]. Below we discuss our comments on a number of proposals regarding payment for advance care planning, chronic care management, transitions of care management, cognitive care services and collaborative care services made in the above- captioned proposed rule. The members of the undersigned societies provide all of the services discussed in this comment letter and we urge CMS to adopt our recommendations.

1. Advance Care Planning (ACP) Services

We support CMS' proposal to establish separate payment for Advance Care Planning (ACP) services using the RUC-recommended physician work and practice expense inputs. The Coalition includes many of the specialty societies that surveyed this code for the RUC and recommended separate payment for CY 2015.

As we have previously commented, there is extensive published clinical evidence supporting the improvement of care when these services are furnished to Medicare beneficiaries who wish to discuss their values and preferences for care.

Recommendation: The Coalition commends CMS for this proposal and strongly recommends that CMS finalize this proposal without modification.

The Coalition strongly opposes any restrictions or conditions of payment for the ACP codes. This is a service that has been demonstrated to improve the quality of care; we share the CMS goal of allowing all Medicare beneficiaries to have unfettered access to these important conversations thereby allowing them to happen when they are needed. Establishing practice eligibility or clinical staff requirements, disease severity or life expectancy criteria or otherwise limiting the service to certain patient

populations or certain types of practices would limit access to this valuable service and undermine our shared goal of improving care through a better understanding of patient values and goals for treatment.

2. Chronic Care Management (CCM) and Transitional Care Management (TCM) Services

The Coalition appreciates CMS' decisions to pay for non-face-to-face management and care coordination services via the Chronic Care Management (CCM) and Transitions of Care Management (TCM) CPT codes (99490 and 99495/99496, respectively). In the proposed rule for 2016, CMS asks for recommendations to reduce the administrative burden of these services. As many of the Societies that originally proposed these codes to CMS and submitted the code change proposals for these codes to the CPT Editorial Panel are signatories to this Coalition letter, we are pleased to make the following recommendations:

CCM Services. Our Coalition continues to believe that the payment for 99490 (chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with required elements) is inadequate to appropriately compensate practices for all the clinical activities and documentation requirements that Medicare established for physicians to bill for CPT code 99490. We hear from our members that CCM is not being utilized as much as it should, given the needs of the chronically ill Medicare population potentially eligible for this service.

Recommendation: The Coalition recommends that CMS recognize CPT code 99487 (complex chronic care management services, at least 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with specified required elements) in addition to 99490. The CPT manual includes guidelines for reporting complex care management services based on the total duration of staff time.

CMS should also adopt the requirements for billing codes 99490 and 99487 as described in the CPT manual:

"Chronic care management services are provided when medical and/or psychosocial needs of the patient require establishing, implementing, revising, or monitoring the care plan. Patients who receive chronic care management services have two or more chronic continuous or episodic health conditions that are expected to last at least 12 months, or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation / decompensation, or functional decline...

Complex chronic care management services are provided during a calendar month that includes criteria for chronic care management services as well as establishment or substantial revision of a comprehensive care plan; medical, functional, and/or psychosocial problems requiring medical decision making of moderate or high complexity...

Physicians or other qualified health care professionals may not report complex chronic care management services if the care plan is unchanged or requires minimal change (e.g. only a medication is changed or an adjustment in a treatment modality is ordered.) Medical decision making as defined in the Evaluation and Management (E/M) guidelines is determined by the problems addressed by the reporting individual during the month.

Patients who require complex chronic care management 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.

Typical adult patients who receive complex chronic care management services are treated with three or more prescription medications and may be receiving other types of therapeutic interventions (e.g. physical therapy, occupational therapy)...

All patients have two or more chronic continuous or episodic health conditions that are expected to last at least 12 months, or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation / decompensation, or functional decline. Typical patients have complex diseases and morbidities and, as a result, demonstrate one or more of the following:

- Need for the coordination of a number of specialties and services;
- Inability to perform activities of daily living and / or cognitive impairment resulting in poor adherence to the treatment plan without substantial assistance from a caregiver;
- Psychiatric and other medical comorbidities... and/or
- Social support requirements or difficulty with access to care."¹

Further, CMS should revise its requirements for use of the EHR to make it clear that facsimiles can be sent from a certified EHR technology in connection with providing CCM. Finally, CMS should establish relative value units (RVUs) for CPT Code 99487 based on the RUC's recommendations to CMS for physician work and practice expense inputs. If CMS adopts these recommendations, payment will be appropriate for the requirements of each code.

TCM Services. The major administrative burden for billing TCM is the requirement that the claim not be submitted until the entire 30-day period for TCM is over. CMS' current policy requires that physicians report the date of service as the 30th day from the date of discharge from the facility. However, these codes require practices to contact the patient within two days of discharge and have a face-to-face visit with the beneficiary within 7 days (99496) or 14 days (99495) of discharge. It is a tremendous obstacle to require providers to wait until the 30th day to bill for the service. This requires practices to calculate the 30-day period, which is different for every patient, and to hold on to claims until well after two of the most important requirements of the code have been met.

Recommendation: The Coalition strongly recommends that CMS allow practices to bill for TCM after the required face-to-face visit is furnished. Further, CMS should define the date of service of the claim to be the day the face-to-face service occurs. Such a policy would be consistent with the policy for submitting claims for 10- and 90-day surgical global services. For those global procedures, the claim is submitted after the surgical procedure is performed. We encourage CMS to adopt a similarly intuitive process for submitting claims for TCM services, which would significantly reduce the administrative burden of reporting these services. Removing the 30 day requirement will facilitate reporting of this

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¹ American Medical Association, CPT Code Manual, 2015.

immensely important service and be a big step forward in improving access to TCM services for Medicare beneficiaries.

Treatment for the Misvalued Services Target. With respect to ACP, CCM and TCM, the Coalition endorses the comments made by the American Medical Association regarding treatment of these services for the misvalued services target.

We are very disappointed to learn that CMS included the services in the net reduction target for CY 2016. The RUC, specialty societies and CMS have worked extremely hard over the past few years to develop several coding solutions that recognize the important components of care management, which lead to better health outcomes for individuals and help to reduce downstream costs within the health care system. Services like the TCM and CCM services represent targeted payment initiatives that were specifically created to provide appropriate support for furnishing the best patient care possible.

Given the implicit nature of services like advance care planning, the AMA and the RUC are disappointed to learn that CMS included these services in the net reduction target for CY 2016. The advance care planning codes represent new services, which are not currently reportable. The RUC estimates that roughly \$4 million will be spent on these services in CY 2016. Creating a scenario in which payment for these services is immediately offset by a reduction in the conversion factor, resulting from not hitting the target, is counterintuitive to the recent work to recognize important care management services.

Recommendation: The Coalition recommend that CMS should estimate the cost of implementation of the advance care planning services as "redistribution" from other services for CY 2016 and not include it in the net reduction target.

3. Improved Payment for the Professional Work of Care Management Services Including Recommendations for Establishing Separate Payment for Collaborative Care

General Comments on the CMS Proposal

In the Proposed Rule, CMS requests comment on new codes for the professional work of care management and for specified types of collaborative care. We support making separate payment for these services as we continue to be concerned that the current E/M codes do not describe a significant number of services that physicians and other qualified health care professionals who provide cognitive care are currently and regularly furnishing to patients with chronic and acute illnesses.

We agree with CMS' proposed approach to establish new codes for services not currently described or paid for under the MPFS and believe is feasible to design new codes that will enable payment for cognitive services that are being performed, but not reimbursed, under current payment policy. Notably, while CMS in the proposed rule suggests that all the new codes for the professional work of care management could be structured as add-ons to existing E/M codes, the Coalition disagrees. While it is possible that some of these services could be add-ons to existing E/M services, we have not identified many services that would be appropriately described as add-on services. Add-on codes must be reported by the same physician who reports the underlying base code and the add on service must be performed on the same day as the base service; however, many of the care coordination and collaborative care services that we perform occur over an episode of care that typically last for many

days. That said, as we discuss below, one possible candidate for an add-on code could be interactive complexity, akin to CPT code 90785. Our specific ideas for code proposals are described further below.

Irrespective of the type of code adopted, it is critical that CMS focus on services that provide additional value and improve the quality of care.

The Coalition has four principal recommendations:

- A. CMS should establish guidelines for creation of new codes for professional work and collaborative care to assist stakeholders in making recommendations.
- B. CMS should establish new HCPCS codes and separate payment for the following services that are not described by existing codes:
 - 1. Collaborative Care
 - Ongoing Collaborative Care Involving Face-To-Face Visits
 - Interprofessional Consultations Without a Face-to-Face Visit
 - Care Provided in a Multidisciplinary Clinic
 - 2. Patients with Acute Illness or on a Course of Chemo- or Immunotherapy
 - Management of Patients on Chemo- or Immunotherapy
 - Non-Face-to-Face Care Provided During an Acute Illness
 - 3. Interactive Complexity
 - 4. Medication Therapy Management and Genetic Counseling Services
 - Medication Therapy Management by Pharmacists
 - Genetic Counseling by Non-Physicians
- C. CMS should recognize and establish separate payment for the collaborative care models for beneficiaries with common behavioral health conditions that it discusses in the proposed rule.
- D. CMS should recognize and make separate payment for the following existing CPT codes:
 - CPT Codes 99358 and 99359 Prolonged Service Without Direct Patient Contact
 - CPT Codes 98960, 98961 and 98962, Education and Training for Patient Self-Management

Our detailed comments on each of these recommendations follow.

A. Recommended Guidelines for Recognizing Existing CPT Codes or Creating New Codes for Unpaid Services

We recommend that CMS establish guidelines for recognizing and making separate payment for new cognitive services going forward. It is very important for stakeholders to have a general idea of CMS' thinking in order to facilitate the provision of helpful recommendations.

Specifically, we believe that CMS should establish the following general guidelines:

- The physician or clinical staff time inherent to new services should be well beyond any pre- and post-service time included in face-to-face visit codes.
- Codes could include minimum physician and/or clinical staff time, as appropriate.
- Codes could include, where appropriate, patient condition criteria related to the severity and acuity of the patient's illness.
- Codes should not include any practice-specific criteria (e.g., certain EMR capabilities) unless those criteria are otherwise required for all physician practices by previous rulemaking.
- Codes may describe special situations that, while uncommon, need to be addressed to assure access to care.

Establishing guidelines such as these will help assure that the new services recognized by CMS are high-value services that improve the quality of care.

Consistent with the above criteria, our Coalition has developed the conceptual and coding proposals below. We would be pleased to work with CMS to develop these ideas further.

Specific Service Concepts and Proposals

We ask that CMS implement the specific service concepts, and in some cases, specific codes, enumerated below in rulemaking for CY 2017. These concepts are critically important for establishing payment for many of the non-reimbursed services commonly being performed by our members and for the transition to alternative payment models. Indeed, we believe these concepts are as important as TCM and CCM.

Establishing separate payment for these services in 2017 will allow physicians to gain experience with them and be better able to use them as they transition to new payment models. As importantly, the ability to report these services would facilitate the transition to alternative payment models by (1) supporting the development and expansion of the infrastructure needed to provide care coordination and collaborative care, (2) facilitating collection of data on non-face-to-face care being provided, (3) better account for physicians' cognitive work for use in developing more accurate payment methodologies, (4) allow existing Accountable Care Organizations (ACOs) to evaluate productivity more accurately, and (5) more easily attribute patients to physicians and ACOs.

Given the limitations of electronic health records, especially in regards to interoperability and the ongoing controversy over meaningful use, the members of this Coalition are not in favor of CMS establishing technology requirements for practices to be eligible to report these services.

The Coalition thanks CMS for recognizing that stakeholders, such as this Coalition, are best positioned to provide suggestions for new codes.

B. Recommendations for New Services for Which Separate Payment Should be Made

Our recommendations for new coding concepts include collaborative care and inter-professional consultations, as well as care provided during a course of chemotherapy or immunotherapy or during an acute illness. We also discuss developing a code for interactive complexity that could be used by non-psychiatrists.

The Coalition understands that the CMS timeline requires that CMS create G codes for CY 2017 as the CPT/RUC calendar does not permit the creation of new codes until CY 2018. However, the Coalition is committed to submitting coding change proposals to the CPT Editorial Panel for the new codes recommended in this comment letter in time for CPT approval, RUC review and CMS adoption in CY 2018. This means that CMS can be confident that any codes it creates for 2017 will be vetted by the medical community and that RUC recommendations will be received in time for CY 2018.

It is important to emphasize that the recommendations below each represent distinct types of services that involve cognitive physician work not currently described by existing codes. In addition to describing the physician cognitive work we also discuss clinical staff activities inherent in these services. Other than interactive complexity, our recommended services would not adequately be described as add-ons to an existing E/M code.

1. Collaborative Care

CMS specifically solicited comments on establishing payments for collaborative care services. We have identified two types of collaborative care that are being commonly provided by many physicians and that are currently not paid separately under the MPFS. These are:

- (1) ongoing collaborative care furnished by a specialist in conjunction with a primary care physician where the specialist sees the patient face-to-face and is caring for the patient's primary condition and the primary care physician is providing support related to the patient's comorbidities. This type of collaborative care has also been called "principal care", and
- (2) specialist consultations where a specialist provides consultative support to a primary care physician on an intermittent or one-time basis but does not see the patient.

The Coalition also identified the multidisciplinary clinic as a type of care where face-to-face care is provided by multiple providers during a clinic visit and which may not always be described or paid appropriately by existing codes.

These types of collaborative care involve very different types and amounts of physician work and clinical staff activities and therefore will require unique coding and valuation.

Ongoing Collaborative Care Involving Face-To-Face Visits

These are non-face-to-face services provided by specialty physicians who are responsible for the care of a patient's primary condition but who are not the patient's primary care physician and are not responsible for coordinating care for all the patient's problems. This is a very common scenario often referred to as "principal care."

Examples include:

- Neurologists caring for patients with epilepsy, multiple sclerosis or Parkinson's disease;
- Rheumatologists caring for patients with active rheumatoid arthritis or systemic lupus erythematosis;
- Gastroenterologists caring for patients with inflammatory bowel disease or cirrhosis;
- Endocrinologists caring for patients with out-of-control diabetes;
- Infectious disease specialists caring for patient with viral hepatitis or Human Immunodeficiency Virus (HIV); and
- Pulmonologists or allergists caring for patients with reactive airway disease.

In each of the above cases, the specialist cares for the patient in conjunction with a primary care physician. The care activities for this service include development and implementation of a disease-specific care plan; patient and caregiver education; and non-face-to-face follow up by clinical staff. The service is differentiated from CCM because the care plan and clinical activities are disease-specific and do not involve coordinating care over a wide range of providers. Furthermore, while these patients may have comorbid chronic conditions, many do not have multiple chronic conditions and would not be eligible for CCM services. These services take place over an extended period of time and are not always associated with a single face-to-face service. Therefore, they are not being appropriately described by add-ons to existing E/M codes.

This type of care involves long term, ongoing collaboration between the specialist and primary care physician where both physicians see the patient for face-to-face visits. The face-to-face visits should be separately billable. While the length of a given episode can vary, it is typical for the collaboration to continue for a minimum of one month. Therefore, payment should be made on a per calendar month basis for as long as the collaborative care is medically necessary.

The Coalition agrees that not all patients followed by specialists should be eligible for this service and that CMS needs to develop illness acuity and/or severity criteria. For example, CMS could require that the disease be of sufficient severity to (1) make patients at high risk of hospitalization or to have been recently hospitalized, (2) require development or revision of the disease-specific care plan, (3) to require frequent adjustments in the medication regimen, and/or (4) management that is unusually complex due to comorbidities or socioeconomic/cultural factors.

CMS should establish a minimum number of activities to be performed by the physician and/or clinical staff under the direction of the physicians. It may also be appropriate to require a minimum amount of clinical staff time spent on activities related to implementing the care plan.

Collaborative care is often provided in a team environment by a group of specialist physicians, thus it may be difficult to tie this code to a single procedure or visit code and it may comprise work provided by

several physicians in a group over time. Therefore, it would be inappropriate to make this an add-on code.

The primary care physician would be expected to bill for CCM, if all the CCM requirements are met, and not for collaborative care; however, there should be no requirement for the primary care physicians to bill CCM in the same month for the specialist to be able to report collaborative care. For example, it may not be medically necessary for the PCP to perform CCM or the PCP may not meet the practice requirements.

Lastly, while levels of service eventually may be necessary, the Coalition believes that CMS should begin implementation of this concept by targeting payment to the sickest Medicare patients who will derive the most benefit from collaborative care. Examples of such patients include those at high risk for hospitalization due to decompensating heart failure or cirrhosis or poorly controlled reactive or obstructive pulmonary disease. CMS should also consider targeting payment to caring for Medicare patients who have a poor prognosis due to socioeconomic or cultural factors that may affect the course of their disease.

Interprofessional Consultations Without a Face-to-Face Visit

These consultations are less frequent than the ongoing collaborative care described above but are also an important service for which separate payment is not made by Medicare. Several time-based CPT codes exist to describe these services: 99446-99449 with the descriptor, *Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional.*

We recognize that several payment policy issues exist which make these codes, as currently described, problematic. These include beneficiary cost-sharing liability and the potential for abuse in the absence of patient eligibility criteria related to disease severity and acuity.

In this context, we note that Medicare does make payment for pathology consultation services under CPT codes 88321, 88323 and 88325. These codes are used with codes for surgical pathology procedures and are strictly for outside, non-face-to-face consult cases.

The CPT manual descriptors are as follows:

88321-- Consultation and report on referred slides prepared elsewhere.

88323 -- Consultation and report on referred material requiring preparation of slides.

88325 -- Consultation, comprehensive, with review of records and specimens, with report on referred material.

These codes all involve non-face-to-face services that require review of medical records, pathology specimens, and production of a written report. As opposed to the surgical pathology codes 88300-88309 where the unit of service is the specimen, for codes 88321-88325 the unit of service is the case (slides, medical records, referring pathology report, etc.). Importantly, the beneficiary liability issues

appear not to be problematic and importantly, these codes are based on complexity, not time. That said, the relationship between a pathologist and a surgeon is different than the interactions between a surgeon and an internal medicine subspecialist which are more likely to be ongoing and involve a number of non-face-to-face consultations over time.

An example of non-face-to-face consultative services is the tumor board. Tumor boards are well-established formal conferences among specialists who provide one-time or intermittent input on a case where one or more of the participants does not see the patient face-to-face. In the case of tumor boards, the specialists may include oncologists, radiologists, pathologists, surgeons, and others involved in managing the malignancy and comorbid (but non-cancerous) chronic conditions. Tumor boards may occur in person, by conference call, real-time interactive video and audio or a combination of the above.

These consultations are different from team conferences in that all participants in team conferences, as defined by CPT, see the patient face-to-face and the purpose is to review on-going care and to evaluate the patient's condition against the previously established care plan or to create a care plan. The consultations described in our recommendation are non-face-to-face and are performed by specialists in order to provide advice for the purpose of establishing a treatment plan or revising a treatment plan when the patient has failed therapy.

The Coalition believes that the value of these consultations lies in the complexity of the medical decision making - not the time required (e.g., to review medical records) or the location of the service (e.g., the consultation could be provided from the consultants home after reviewing records electronically).

Therefore, the Coalition believes that the existing CPT codes 99446-99449 do not adequately describe these consultations and may need to be replaced or revised. We intend to continue reviewing these issues and would be pleased to work with CMS to develop codes for these important services in time for the CY 2017 proposed rule.

Multidisciplinary Clinic

Over the last several years a new model of providing care to patients with complex chronic conditions has emerged. This model is called the "Multidisciplinary Clinic," which requires the ongoing, simultaneous, involvement of two or more physicians from different specialties. In this care model, physicians from different specialties see patients simultaneously and share the history-taking, physical examination and medical decision-making. An example is a musculoskeletal clinic where rheumatologists, orthopedists and physiatrists see patients together and where clinical staff with specialized training in the care of complex patients are involved.

The Coalition understands that many physicians are using E/M codes to describe services provided during these visits. We intend to continue reviewing the reporting of services in these clinics to determine whether there are situations where current E/M coding would not adequately or accurately describe the services provided and will make recommendations to CMS if the services that are not E/M can be more accurately described.

2. Patients with Acute Illness or on a Course of Chemo- or Immunotherapy

Management of Patients on Chemo- or Immunotherapy

The Coalition recommends that CMS begin making payment for services provided by any physician or practice that is managing patients during a course of chemo or immunotherapy that is medically necessary for treatment of an underlying disease such as cancer, inflammatory bowel disease or rheumatoid arthritis. While this form of therapy has historically been provided by oncologists, the development of disease-modifying biologics for non-oncologic illness has required other specialists to administer such treatments.

Management of patients on chemo- or immunotherapy is complex and requires significant clinical staff time to be spent on patient/caregiver education, non-face-to-face follow up between cycles of medication administration, and development and revision of a disease-specific care plan. The physician work and clinical staff activities involved in this service are different from the work involved in ongoing collaborative care (as described above) and should be recognized by a distinct code with appropriate payment. These differences are due to the nature of the therapy, the lack of involvement of a primary care physician, and differences in disease acuity and severity. Therefore, we agree that collaborative care services cannot be reported at the same time as chemo- or immunotherapy management services.

The Coalition would be pleased to work with CMS on development of a code for this important service in time for the CY 2017 rulemaking cycle. Because these services are provided over time in connection with more than one administration service, it would not be appropriate to describe them with an add-on code. Issues that need to be addressed include the need to differentiate 1) initial and subsequent management services, 2) chemo-from immunotherapy, 3) the duration of the service (e.g., per calendar month, per course of treatment), 4) the appropriate clinical staff mix (e.g., specially trained RNs, pharmacists), and 5) the required clinical staff time and activities.

Non-Face-to-Face Care Provided During an Acute Illness

The Coalition has identified this service as becoming more and more important as patients increasingly are being cared for at home or other places for acute illnesses that have historically been taken care of in the physician office or hospital. This shift in care is due to a number of factors; the Coalition wishes to focus on two of them: (1) the increasing number of patients who wish to be taken care of at home and who have medically knowledgeable caregivers, and (2) the inability of many patients to come to the physician office (e.g., living in rural areas, inability to obtain transportation, etc.).

Typically, these services are provided by a physician, with clinical staff under the supervision of the physician when necessary, interacting with a patient or caregiver and other professionals to monitor and revise care for an acute illness that places the patient at high risk for hospitalization. Services may be provided over the phone, by email or by real-time interactive video and audio and may include review of biometric monitoring. Examples include caring for patients with pyelonephritis, pneumonia, heart failure, and inflammatory bowel disease or autoimmune disease.

While these services may be provided after a face-to-face visit that is separately reportable, in many cases no face-to-face visit occurs (e.g., a visiting nurse discovers an infection during a routine visit and

contacts the patient's primary care doctor to initiate treatment). Therefore, the performance of a face-to-face visit should not be required in order to report this service.

The Coalition agrees that only a single practice would report this service for an episode of care and due to the likelihood that no face-to-face service is provided and the potential involvement of two or more physicians in the group being involved in the care, it would be inappropriate to make this service an add-on to existing E/M services.

The physician work of these services is different from collaborative or chronic care services because only one physician or practice is involved in the care and the focus is on treating an acute illness over a shorter period of time; furthermore, this service would rarely, if ever, involve creation or revision of a care plan and there may not be the need to coordinate care among different providers.

Importantly, and consistent with the guidelines we recommended, this work goes well beyond the preand post-service work of any face-to-face visit that may occur during the acute illness. That said, we recognize the need to develop disease acuity and severity criteria, and to define minimum time and activity requirements for physician or clinical staff. These services are usually provided over 7-14 days and should include all non-face-to-face care furnished over that period. CCM and collaborative care should not be reported if performed during the time acute care services are provided.

In addition, these services are distinct from the non-face-to-face prolonged service codes, which are intended to be reported for prolonged pre- or post- service review of medical records or other data directly related to a face-to-face visit. The prolonged service codes are not intended to describe provision of care by a medical practice over 7-14 days to acutely ill patients.

The Coalition believes that two different codes are needed, 1) for patients living in a non-facility setting such as their home or an assisted living facility and 2) for patients in skilled nursing and other facilities that employ clinical staff to support the provision of these services. The practice expense inputs for the two settings of care differ, hence the need for two codes.

3. Interactive Complexity

The Coalition recommends that CMS establish a code for non-psychiatric interactive complexity. The Coalition reviewed CPT code 90785 (interactive complexity, list separately in addition to the code for primary procedures) that is reported by psychiatrists. The Coalition believes that CMS should establish a similar code for non-psychiatrists because many of the same complex communication and interaction issues arise in patients with non-psychiatric diseases.

The CPT code descriptor for 90785 includes the following:

"With interactive complexity" may be reported when one or more of the following is present:

- 1. The need to manage maladaptive communication... among participants that complicates delivery of care.
- 2. Caregiver emotions or behavior that interferes with the caregiver's understanding and ability to assist in the implementation of the treatment plan.

- 3. Evidence or disclosure of a sentinel event and mandated report to third party (e.g. abuse or neglect with repot to state agency) with initiation of discussion of the sentinel event and / or report with patient and other visit participants.
- 4. Use of play equipment, other physical devices, interpreter, or translator to communication with the patient to overcome barriers between the physician or other qualified healthcare professional and a patient who:
- Is not fluent in the same language... or
- Has not developed, or has lost, either the expressive language communication skills to explain his or her symptoms and response to treatment, or the receptive communication skills to understand the physician or other qualified health care professional if he or she were to use typical language for communication.

A similar code for non-psychiatric cognitive specialties could reflect the added intensity of services provided to patients with communication difficulties that result in highly complex interactions and discussions between physicians and caregivers about the patient's medical condition.

The Coalition believes that the issues faced by non-psychiatrists are different from 90785 and require other types of physician work. For example, patients with dementia are unreliable historians and significant time must be spent obtaining the patient history and functional status information from caregivers who may be naïve about the patient's medical problems and medically unsophisticated. These interactions require significant time and are more intense than the typical patient visit.

That said, the time required to provide these services is not typically long enough to allow reporting of the prolonged face-to-face services code(s). Creating a code for interactive complexity would allow physicians to report unusually intense and prolonged E/M services where the physician work is well beyond that of the typical E/M but the time is insufficient to report the prolonged services codes.

The need for this code notwithstanding, the Coalition recognizes there are a number of patient/caregiver, medical severity/acuity and other eligibility requirements that need to be addressed before such a code could be established. The Coalition will continue to review these issues and intends to submit a coding proposal to the CPT Editorial Panel for this add-on service.

4. Medication Management and Genetic Counseling Services

The Coalition believes that CMS should explore opportunities to apply its regulatory discretion to pay for medication therapy management and genetic counseling services when they are provided incident to the service of a physician. We recommend that CMS pay separately for the following existing CPT codes and services:

99605 - 99607: Medication therapy management services provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided...and

96040: medical genetics and genetic counseling services, each 30 minutes face-to-face with patient / family

The CPT Manual states that medication therapy monitoring is provided to optimize the response to medications or to manage treatment-related medication interactions or complications and include the following documented elements:

- Review of the pertinent patient history
- Medication profile (prescription and non-prescription)
- Recommendations for improving health outcomes and treatment compliance.

The manual also states that these codes are not to be used to describe the provision of product-specific information at the point of dispensing or any other routine dispensing-related activities.

The CPT manual says that genetic counseling services are provided by trained genetic counselors - not physicians - and may include:

- Obtaining a structured family genetic history
- Pedigree construction
- Analysis for genetic risk assessment
- Counseling of the patient and family.

The manual also states that these activities may include review of medical data and family information, face-to-face interviews, and counseling services.

We note that while medication therapy management services are part of Medicare Part D already, there are no practice expense inputs for these services under Part B. The services of genetic counselors are not separately paid but are becoming increasingly important to the delivery of personalized diagnostics and therapeutics. We recognize the inherent difficulty of recognizing these non-physician health care professionals absent legislative action, but recommend that CMS explore the possibility of paying for these services when they are provided incident to a physician's service and by using the Center for Medicare and Medicaid Innovation's demonstration authority to do so.

C. Collaborative Care Models for Beneficiaries with Common Behavioral Health Conditions

CMS solicits recommendations for establishing payment for a specific, evidence-based model of collaborative care for behavioral health conditions. The Coalition supports the comments made by the American Psychiatric Association to this proposed rule.

The Collaborative Care Model (CoCM) is a team approach that gives patients seen in primary care settings access to behavioral health care that is effective both clinically and economically. In this approach, primary care providers treating patients with common behavioral health problems are supported by a behavioral health care manager and a psychiatric consultant who help implement effective, evidence-based treatment for common behavioral health problems in the primary care setting.

The Collaborative Care Model includes these three basic elements:

1. Care management and treatment specific to the patient's behavioral health condition;

- 2. Regular, proactive outcome monitoring and treatment to target using validated clinical rating scales; and
- 3. Regular, systematic psychiatric reviews of the entire caseload and consultation for patients who do not show clinical improvement.

In discussing the coding proposition for this model, it is essential to recognize that the CoCM is a population-based model of care for a category of health conditions and that it has defined protocols. It is this specific model that has been thoroughly evaluated and has a published evidence base.

The Coalition believes that the work of all three practitioners needs to be accurately described and reimbursed. There are two key issues to be addressed: (1) should this work be paid using a single code or different codes? and (2) because the services provided by the psychiatrist include population management as well as individual patient care, how can payment reflect the work associated with population management be billed if it is not tied to individual patient care?

Additional issues to consider include: ensuring no overlap of services between CoCM and existing E/M services; qualifications of the care providers; minimum time requirements and care activities that need to be documented for billing; differentiation of these services from CCM services; and the need for beneficiary awareness and consent.

While the Coalition is not prepared at this time to make specific recommendations with regard to this proposal, we believe that these issues can be resolved with additional time and consideration, and look forward to working with CMS to establish appropriate coding and payment policy for this important and valuable service.

D. Recommendations for Recognizing Existing CPT Codes for Which Separate Payment is Not Being Made Under the MPFS

The Coalition recommends that CMS recognize certain existing codes as part of its initiative to improve payment for care coordination. The Coalition believes that the following codes can be implemented with minimal additional payment policy because the CPT language and descriptors are clear and provide adequate guidance for accurate reporting of these services.

CPT Codes 99358 and 99359 - Prolonged Service Without Direct Patient Contact.

These codes describe significant additional non-face-to-face work performed by the physician in the review of medical records and other clinical information. These services are needed to care for patients with chronic illnesses that are complex and/or patients who are severely ill and have multiple comorbid conditions.

The most common use of these codes is to review extensive medical records, such as before or after a patient's office visit, or upon a patient's admission to or discharge from a facility. They are also used when it is necessary to review extensive diagnostic information and consult with other physicians such as radiologists and pathologists.

Importantly, while related to a face-to-face E/M visit, the time spent on this service may be on a different date than the E/M. The physician work and time clearly goes beyond the pre- and post-service

physician work and time of any face-to-face E/M visit. The CPT instructions for use of these codes and the time requirements are clear and well understood by the physician community. These codes have been valued by the RUC and we recommend that CMS recognize these codes for separate payment, recognize the CPT instructions for use, and adopt the RUC recommendations when assigning RVUs. Notably, these codes represent stand-alone services and are not appropriate for add-ons to existing E/M codes.

CPT Codes 98960, 98961 and 98962, Education and Training for Patient Self-Management.

Due to the ever larger number of patients with multiple chronic conditions and/or who require the assistance of caregivers, it is becoming increasingly important for clinical staff under the supervision of the physician to train patients and caregivers to manage chronic illnesses at home. This is especially true for patients on multiple medications who must be educated about medication interactions, adverse events and the effect of diet and lifestyle on their conditions and medications.

For example, patients with dementia, and their caregivers, must be educated as to safety and functional status issues as the patient's cognitive function declines over time. While some of this education is performed over the phone by clinical staff and can be reported using CPT Code 99490, the CCM code, in many cases the education occurs during or immediately following a face-to-face visit when the treatment plan has been initiated and/or revised and the changes are fresh in the patient's mind. Face-to-face patient and caregiver education on the same date as an E/M service cannot be reported using 99490, the CCM code.

CPT Codes 98960-98962 are used to report education and training performed by clinical staff - not physicians. The education for self-management codes are well understood by the medical community. The CPT instructions for these codes are clear and well understood and they have been valued by the RUC. The type of education we believe should be reimbursed separately goes well beyond any staff education provided as part of an E/M service (e.g., education reportable under CPT code 99211). In addition, this service may be performed on a day where no other E/M is provided so it is not appropriately described using an add-on to an E/M code.

We thank CMS for the opportunity to comment on this proposed rule. Please call Alanna Goldstein at the American Geriatrics Society at 212-308-1414 or Paul Rudolf at Arnold & Porter at 202-942-6426 if you have any questions about these comments.

Signed:

- Advocacy Council of the American College of Allergy, Asthma and Immunology
- AMDA The Society for Post Acute and Long Term Care Medicine
- American Academy of Allergy, Asthma, and Immunology
- American Academy of Home Care Medicine
- American Academy of Hospice and Palliative Medicine
- American Academy of Neurology
- American College of Allergy, Asthma and Immunology

- American College of Rheumatology
- American Gastroenterological Association
- American Geriatrics Society
- American Psychiatric Association
- American Society for Blood and Marrow Transplantation
- Infectious Diseases Society of America