

August 29, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Re: 42 CFR Parts 403, 405, 410, et al. 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; Proposed Rule

Dear Ms. Tavenner:

On behalf of the American College of Physicians, I am writing to share our comments on the proposed rule for the Calendar Year 2015 Medicare Physician Fee Schedule. ACP is the largest physician medical specialty society, and the second largest physician membership organization, in the United States. ACP members include 141,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness. The College thanks the Centers for Medicare and Medicaid Services (CMS) for this opportunity to address this notice of proposed rulemaking publicly.

In the Medicare Physician Fee Schedule notice of proposed rulemaking for 2015, CMS proposes a number of changes to its physician fee schedule rules, including adding coverage for chronic care management, changes to the open payments program, and changes to the Medicare Shared Savings Program and Value Based Modifier and Physician Feedback Program. ACP appreciates the effort that CMS is making to reform the Medicare Physician Fee Schedule, for the better capture of the wide breadth of care while keeping care quality in consideration. However, we urge CMS to step back and review the physician fee schedule as a whole rather than just as individual components. Physicians in all settings, but particularly in small practices, have to digest all of this information, determine which elements apply to them, and then figure out the changes they have to make in their practices to comply with all of the relevant components. This is on top of all the other constantly changing requirements that CMS and other payers ask of these practices. It is tremendously difficult for physicians to know what exactly to do—and if they determine what to do, then they must find the time to carry it out while still providing high quality care to their patients and managing the other day-to-day activities and business aspects of their practice.

I. Summary of ACP Recommendations

Throughout this letter, ACP provides a number of recommendations to CMS in order to improve the final 2015 Medicare physician fee schedule. Our top priority recommendations are summarized below and discussed in greater detail within this letter.

Chronic Care Management

- ACP would like to thank CMS for the time and attention you have spent in the last several months refining the scope of services for CCM; however, the College has some concerns about the proposed payment amount for CCM code GXXX1 as a stand-alone code and would therefore like to propose a series of alternative options for CMS' consideration:
 - **ACP strongly recommends (as Option 1) that CMS accept and reimburse CPT code 99490 based on valuation proposed by the Relative Value Scale Update Committee (RUC).**
 - **If recognizing and valuing 99490X as described above is not desirable by CMS, then the College recommends (as Option 2) that CMS reinstate their original proposal from July 2013 (i.e., the 2014 Proposed Rule) for two codes, GXXX1 and GXXX2. ACP further recommends that the values for the code GXXX2 describe each additional 20 minutes of service (not to exceed 40 additional minutes per 30 days) with the same values proposed for code GXXX1 (i.e., an RVU of 0.61 for each additional 20 minutes of clinical staff time).**
 - **If CMS were to finalize only one G code (GXXX1), then as a third option, the College recommends that CMS designate the 30-minute timeframe with 1 RVU and a simplification of the proposed requirements.** This 30 minute timeframe with 1 RVU and the simplification of requirements is important both to patient care and to providing an incentive for physicians. It is critical that the CCM code include a sufficient amount of physician work time (including non-face-to-face time) and clinical staff time in order to encourage its use.
 - **We also highlight that the options available to CMS are not mutually exclusive. For example, CMS could recognize both codes 99490X and one or more of the G codes, to gain experience with different forms and valuations of chronic care management.**
 - **Additionally, CMS should delineate the minimum documentation standards of the clinical staff time required to report chronic care management services; and articulate the acceptable activities of the clinical staff that may accrue to the minimal time standards.**
- **The College recommends that CMS carefully analyze its policy decision to exclude clinicians participating in the Multi-Payer Advanced Primary Care Demonstration and the Comprehensive Primary Care Initiative from billing for chronic care management.** It is critical to ensure that Multi-Payer Advanced Primary Care Demonstration and the Comprehensive Primary Care Initiative participants are not put at a disadvantage compared to their colleagues that are not participating in these models, but who will be able to bill for the CCM code
- **If a comprehensive care plan is a prerequisite to billing for CCM services, the College would like to see examples of acceptable and unacceptable practices, as well as a realistic assessment of who would create such care plans and the time it would take to do so.** The College is concerned that these requirements are overly prescriptive and may make it impossible for chronic care management to work. Additionally, a care plan does not need to be comprehensive to be useful. It can be about one issue with shared decision making towards a goal – such as how and when to stop smoking. The key elements of a useful care plan are clarity and shared decision making.

- The 2014 CEHRT specifications do not provide a way to share a care plan with team members who do not have access to the coordinating physician's EHR system. Additionally, the version of C-CDA that is specified in the 2014 Edition certification criteria is version 1.1. However, C-CDA 1.1 does not include a care plan per se. Therefore, we offer the following recommendations:
 - **CMS should offer tools that will genuinely help clinicians manage the planning of the care of their patients.**
 - **CMS should wait until C-CDA version 2 has been implemented and, moreover, used successfully in the field before requiring clinicians to use it for care planning. It will be several years before we know if this is the best way to manage care plans. Criteria to measure the success of the use of C-CDA version 2 implementations should include structured data related to each of the elements specified above from the S&I Framework Transitions of Care and Long-term Care Coordination groups. Criteria should also include measures of successful outcomes related to the use of such data.**
 - **ACP supports CCM services, other than care plans, being performed with the use of EHRs or other health IT information exchange platforms. However, having EHRs available with total interoperability 24 hours, 7 days a week is not currently possible. Therefore the College strongly recommends that CMS not require that the EHR be able to share electronic data or be accessible to all clinicians providing care during and after normal business hours.**

Resource-Based Practice Expense (PE) Relative Value Units (RVUs) Proposal

- The College maintains its position of not supporting provider-based billing for care delivered in an outpatient, hospital-system owned practice when that care is not dependent on the hospital facility and its associated technologies. Rather, in line with the College's high value care initiative, the College supports delivery of care in the most efficient setting, while maintaining quality of care.

Potentially Misvalued Services Under the Physician Fee Schedule

- ACP recommends the following options for CMS' consideration regarding Obesity Behavioral Group counseling:
 - Method 1: Conclude that a group of 5-10 patients will require 60 minutes with a total RVU of 1.8.
 - Method 2: Another potential solution would be to create the codes as add-ons, similar to the cryotherapy codes.

Concerns with the 10- and 90- Day Global Packages

- ACP agrees with and supports the agency's decision to transition all 10- and 90- day global codes to 0-day global codes.

Valuing New, Revised, and Potentially Misvalued Codes

- **ACP recommends that CMS not make January 15 of each year the required deadline for submitting RUC recommendations to be included in the following year's Medicare Physician Fee Schedule.**
- **Additionally, ACP recommends retaining the current CPT/RUC meeting infrastructure, while shifting the workflow of the meetings in order to accommodate the Agency's rulemaking process. ACP further recommends that the CMS wait to begin implementing the new timeline until the 2017 Medicare Physician Fee Schedule.**

Reports of Payments or Transfers of Value to Covered Recipients (Proposed Changes to the Open Payments Program)

- The College believes the solution being proposed by CMS is inadequate—it is both overly stringent and not stringent enough at the same time. **Thus, the College suggests that CMS either:**
 - **withdraws the current proposed modification and maintains the current approach that provides a clear standard for approval and offers reasonable protections from undue industry influence, or**
 - **implements an alternative approach, briefly discussed in the proposed rule, in which CMS develops a list of standards (criteria) required for the reporting exclusion that ensures the independence of the continuing education activities such as the Standards for Commercial Support: Standards to Ensure Independence in CME Activities used by the Accreditation Council for Continuing Medical Education**

Medicare Shared Savings Program

- The College supports the proposed additions and eliminations to the current set of quality measures, with a few exceptions and concerns, including:
 - The College suggests that the proposed “All-Cause Unplanned Admissions for Patients with Diabetes Mellitus (DM), Heart Failure (HF) and Multiple Chronic Conditions” measures are underdeveloped and could benefit from further modification to improve clarity and reliability.
 - **The College, while in support of adding mental health measures, is concerned that the “Depression Remission at Twelve Months” measure may be burdensome to obtain and reflect a standard that is too difficult to meet.**
 - The College, while recognizing the importance of patient experience of care measures, questions the appropriateness of the proposed “Stewardship of Patient Resources” measure, which assesses whether the patient recalls any discussion of the cost of medications prescribed. Such discussions, while appropriate for “high tier,” costly medications, are of questionable value relative to measuring patient-centered, quality care delivery for more frequently prescribed, lower cost, generic medications. **Since the proposed measure does not differentiate between these categories, the College believes it should be removed or significantly modified to reflect this distinction.**
- The College also supports CMS’ proposal to enhance its current quality scoring strategy by explicitly recognizing and rewarding MSSPs that make year-to-year improvements in their quality performance. **However, we are suggesting that CMS consider increasing the number of potential bonus points (e.g. to 4 per domain) that can be earned.**

Physician Compare

- ACP is supportive of the proposal to have all measures be available for download and to only include a select group of measures on the webpage. ACP also supports working with consumer groups to identify the meaningful measures for consumers and encourages CMS to ensure that measures on the webpage remain patient centered and reflect potential differences in risk/benefit for specific populations.
- **The College emphasizes the importance of physicians and other health care professionals having timely access to performance information prior to public reporting and a fair chance to examine and appeal potential inaccuracies.**

Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System

- ACP encourages CMS to monitor and work with the EHR vendor community to ensure that the EHR vendors are able to report a large number of measures, as recently many of the certified systems have cut back on the number of measures that they support

Value-Based Payment Modifier and Physician Feedback Program

- Due to continuing low participation rates in PQRS among physicians and non-physician EPs¹, ACP strongly recommends that CMS use the next year to engage in outreach to all practices to encourage them to participate in the PQRS program and work to increase PQRS participation rates.
- The College is not supportive of the proposal to increase the amount of payment at risk from 2.0 percent to 4.0 percent in CY 2017. As proposed, a 4% reduction would be applied to groups that fall into Category 2. This would be in addition to the PQRS 2% reduction and would likely have a significant impact on all practices, especially small ones.
- ACP appreciates the alignment between the PQRS and VBP program. **In addition, ACP encourages CMS to explore appropriate ways to adjust quality and cost scores for socioeconomic status and location of care to ensure accurate physician-to-physician comparison groups.**

II. Chronic Care Management (CCM) Proposal

The Centers for Medicare and Medicaid Services (CMS) remains committed to CCM. Much of the scope of service for this code was finalized in the CY 2014 final rule. The work RVUs for CCM code GXXX1 is proposed to be 0.61, down from the 1 work RVU that was recommended by the RUC for the CPT code 99490X, therefore, the estimated payment for code GXXX1 is \$43.67. The details of this code are outlined below:

- CCM is defined by CMS as “chronic care management services furnished to patients with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline.”
- GXXX1; 20 minutes or more; per 30 days
- A clinician who meets the practice standards to bill for chronic care management services may initiate services with an eligible beneficiary as a part of an Annual Wellness Visit (AWV), an Initial Preventive Physical Exam (IPPE), or a comprehensive E/M visit. Along with clinical benefits, the proposed approach of initiating CCM services via AWV or IPPE provides an administrative benefit. It allows CMS to know which clinician the beneficiary has chosen to furnish CCM services, therefore minimizing the chance that multiple clinicians would be providing the same service to the same patient.
- The clinician providing this service must:

¹ 2012 Physician Quality Reporting System (PQRS) and Electronic Prescribing (eRx) Experience Report. Accessed online at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/AnalysisAndPayment.html>

- Provide 24/7 access to the patient in order to address his/her acute chronic care needs. The patient would be given a means to contact the practice's clinicians in a timely manner. Members of the chronic care team must have access to the patient's full electronic medical record, even when the office itself is closed;
- Provide continuity of care with a designated clinician or member of the care team with whom the patient would be able to obtain successive routine appointments;
- Conduct a systematic assessment of the patient's medical, functional, and psychosocial needs;
- Undertake system-based approaches to ensure timely receipt of all recommended preventive care services;
- Conduct medication reconciliation with review of adherence and potential interactions;
- Provide oversight of patient self-management of medications;
- Develop a comprehensive, patient-centered care plan written in consultation with the patient and with other key clinicians who are treating the patient, based on physical, mental, cognitive, psychosocial, functional, and environmental assessment and reassessment and an inventory of resources and supports, assuring that the care provided is harmonized with the patient's wishes and values;
- Manage care transitions within health care, including referrals to other clinicians, visits that follow an emergency department visit, and visits following discharge from hospitals and skilled nursing facilities;
- Coordinate with home- and community-based clinical services; and
- Provide enhanced opportunities for the patient to communicate with the clinician, to include not only the telephone but also secure messaging, Internet communication or other same-time consultation methods.

ACP Comment:

ACP would like to thank CMS for the time and attention you have spent in the last several months refining the scope of services for CCM. We appreciate your interest in focusing on optimizing health and quality of life for individuals with multiple chronic conditions.

In CMS' original proposal, ACP raised a number of concerns regarding the practice standards, specifically the direct hiring of a nurse practitioner (NP), and the direct supervision of clinical staff. ACP appreciates and supports the proposed changes regarding the practice standards:

- The proposed removal of the requirement that clinical staff participating in the chronic care management of a patient be direct hires of the physician or the practice.
- Proposing to allow clinical staff time under general supervision to be counted towards chronic care management at any time of day (even outside of normal business hours) as long it meets the general supervision requirements.

ACP understands the difficult task of CMS to promote better health for individual and reduce expenditure growth. As noted above, the College is in support of the initiatives designed to improve payments and encourage long-term investments in care management services such as CCM. However, ACP has some concerns about the proposed payment amount for CCM code GXXX1 as a stand-alone code and would therefore like to propose a series of alternative options for CMS' consideration. Specifically, these concerns and alternative proposals are as follows:

- In the Medicare Physician Fee Schedule Final Rule for Calendar Year 2014, CMS announced that it had decided to create a CCM service effective January 1, 2015, and finalized a proposal to establish code GXXX1 to describe the service. The proposed RVUs of 0.61 with 20 minutes of clinical staff time may reduce expenditure growth but ACP is not confident that it will encourage long-term investments in the care management services for patients with multiple chronic conditions. Alternatively, a new CPT code (99490X) has also been established for CCM. The new CPT code for CCM has the same descriptor (*Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, Comprehensive care plan established, implemented, revised, or monitored. (Chronic care management services of less than 20 minutes duration, in a calendar month, are not reported separately)*) as code GXXX1 established by CMS. However, CPT code 99490X was valued by the RUC for 1 RVU with 60 minutes of clinical staff time, typically provided by a registered nurse. ACP believes that the valuation of this new CPT code is better aligned with the objectives of CMS in promoting better health for individuals, reducing expenditure growth, and encouraging long-term investments in care management services such as CCM. It is important to note that the development of CPT code 99490X was built on the standards and objectives that CMS published in the 2014 proposed and final rules. In those rules CMS states that, to furnish chronic care management, complex and multidisciplinary modalities are involved, such as: regular physician development and/or revision of care plan; subsequent reports of patient status; review of laboratory and other studies; communication with other health professionals not employed in the same practice who are involved in patient care; integration of new information into the care plan; and/or adjustment of medical therapy. CPT code 99490X was developed with these standards and objectives in mind and with an understanding that successful efforts to improve chronic care management for patients should improve the quality of care while simultaneously decreasing cost (for example, through reduction in hospitalizations, use of post-acute care services, and emergency department visits). **Therefore, ACP strongly recommends (as Option 1) that CMS accept and reimburse CPT code 99490 based on valuation proposed by the Relative Value Scale Update Committee (RUC).**
- Additionally, it is important to keep in mind that both 99490X and GXXX1 as stand-alone codes are reported only once no matter how much physician and staff time is spent performing the service, after the minimum of 20 minutes of clinical staff time has been reached. If significantly more non-face-to-face time than the specified 20 minutes is needed during the billing month, then there would be no means of billing for that physician work, clinical staff time, and the related practice expenses. For patients that are frail with more severe multiple chronic conditions, time spent by clinical staff will unquestionably reach 45 to 60 minutes. Therefore ACP views the proposed RVU of 0.61 as insufficient, since such a low RVU devalues the extremely important and necessary involvement of the physician in supervising chronic care management services. An RVU of only 0.61 with 20 minutes of clinical staff time accounted for will adversely impact the overall valuation (and ultimately the payment amount) for the CCM code, and discourage the long term transformation of primary care practices to deliver such non-face-to-face services. In order to meet the needs of physician practices, particularly small practices, and to encourage involvement in chronic care management services, a valuation that truly incentivizes clinicians is needed—one that is based on the resources required to perform chronic care management. **Therefore, if recognizing and valuing 99490X as described above is not desirable by CMS, then**

the College recommends (as Option 2) that CMS reinstate their original proposal from July 2013 (i.e., the 2014 Proposed Rule) for two codes, GXXX1 and GXXX2. This original proposal provided a means for compensation if significantly more non-face-to-face time than the specified 20 minutes is needed during the 30 day period. ACP further recommends that the values for the code GXXX2 describe each additional 20 minutes of service (not to exceed 40 additional minutes per 30 days) with the same values proposed for code GXXX1 (i.e., an RVU of 0.61 for each additional 20 minutes of clinical staff time). This would allow for 0.61 work RVUs for the initial 20 minutes of time spent with the patients having multiple chronic conditions and 0.61 additional work RVUs for the physician supervision and oversight of each additional 20 minutes of time for patients that require more time and additional resources.

- Thirdly, as noted above, CMS is only proposing 20 minutes of clinical staff time for a single G code (GXXX1). This is particularly concerning, due to the practice expense involved in this code (independent of the time) being quite significant. Again, ACP would like for CMS to encourage long-term investment in care management services by the use of CCM by appropriately valuing the CCM code. In Option 1 above, ACP asks that CMS accept and reimburse CPT code 99490X based on the values proposed by the RUC as most preferred approach. As an alternative, in Option 2 above, ACP asks that CMS reinstate their original proposal of two codes at the proposed values with the add-on code GXXX2 allowing for each additional 20 minutes. In a letter to CMS from ACP dated January 27, 2014, in response to the information published in the 2014 final rule, the College recommended that CMS designate a 30 minute timeframe for clinical staff time. The RUC survey data are available to substantiate the need of at least 30 minutes of clinical staff time to perform CCM. The CPT code 99489 was surveyed by the RUC with respondents noting that 30 minutes of clinical staff time would be expended in performing CCM. **Therefore, if CMS were to finalize only one G code (GXXX1), then as a third option, the College recommends that CMS designate the 30-minute timeframe with 1 RVU and a simplification of the proposed requirements.** This 30 minute timeframe with 1 RVU and the simplification of requirements is important both to patient care and to providing an incentive for physicians. It is critical that the CCM code include a sufficient amount of physician work time (including non-face-to-face time) and clinical staff time in order to encourage its use. ACP also supports the simplification of requirements that are duplicative (e.g., the requirement to manage care transitions within health care is already incorporated in the scope of the transitional care management (TCM) code) and/or requirements that add unnecessary practice expenses and administrative burdens onto physicians. For example, secure messaging or other secure internet-based communication services are, at present, difficult and expensive to implement and operate; and there is no agreed-upon standard way that this can be done. Practices would likely implement different systems, thus increasing costs and confusion among patients who are dealing with more than one practice. The Direct protocol has been proposed as a common method of exchanging secure email among providers and patients; however, Direct has proven more complicated and expensive to implement than initially thought, with a single link costing a practice thousands of dollars plus ongoing maintenance costs. Additionally, not all Direct hubs are able to communicate with each other, thus increasing the likelihood that a practice would have to implement more than one connection. Finally, there is currently no way to authenticate and grant access to patients on a large scale.

The College believes the simplification of requirements such as those outlined above will lessen the administrative burdens, while still maintaining the integrity of the chronic care management service. **A more detailed description of our recommendations for requirement simplification,**

and methods in which to do so, is listed in the comments under, “Health Information Technology for CCM.”

We also highlight that the options available to CMS are not mutually exclusive. For example, CMS could recognize both codes 99490X and one or more of the G codes, to gain experience with different forms and valuations of chronic care management.

Lastly, CMS should delineate the minimum documentation standards of the clinical staff time required to report chronic care management services; and articulate the acceptable activities of the clinical staff that may accrue to the minimal time standards. A model of such specifications exists for the current care plan oversight codes (G0181 and G0182). As part of the routine program processes safeguarding the integrity of the Medicare program, these services will certainly undergo future scrutiny and providers need to understand all of the expected documentation requirements.

Comprehensive Primary Care Initiative (CMMI) / Patient Centered Medical Home (PCMH)

In the rule, CMS is also proposing that clinicians participating in the Multi-Payer Advanced Primary Care Demonstration and the Comprehensive Primary Care Initiative would not be able to bill for chronic care management.

ACP Comment:

ACP understands that duplicative payments would be inappropriate and respects that CMS acknowledges there may be appropriate opportunities for clinicians participating in the demonstration models to use the chronic care management code, even though this may be a limited number. However, ACP is concerned that this exclusion may be discouraging to those participating in the Innovation Center models, particularly as these models do still involve a strong fee-for-service payment component. **Therefore, the College recommends that CMS carefully analyze this policy decision to determine if the Multi-Payer Advanced Primary Care Demonstration and the Comprehensive Primary Care Initiative participants are put at a disadvantage compared to their colleagues that are not participating in these models, but who will be able to bill for the CCM code (i.e., will those non-participating practices be able to obtain a higher reimbursement overall by billing the CCM code than their colleagues engaged in the Innovation Center alternative payment model programs, particularly when the Innovation Center participants are required to meet significantly higher practice standards).** While, as discussed above, ACP is supportive of CMS’ movement toward paying for CCM within the physician fee schedule, it is critical that any approaches taken within Medicare fee-for-service not have unintended negative effects on alternative payment models that ACP believes are making great strides toward true delivery system reform and payment for value rather than volume.

Additionally, ACP would like to reiterate its feedback provided to CMS during the 2014 physician fee schedule rulemaking process regarding patient-centered medical home (PCMH) practices, which are prevalent across the country and are not limited to Innovation Center projects. First, ACP recommends that practices that have achieved independent certification or recognition as a PCMH or PCMH specialty practice be recognized by CMS as able to bill and be reimbursed for this new CCM code without having to provide additional documentation to demonstrate that they satisfy the agency’s criteria or standards. We also specifically recommend that CMS “deem” PCMH and PCMH Specialty Practice recognition programs that provide independent certification of practices as being equivalent to satisfying the final practice capability standards that CMS establishes for the CCM code. The College further recommends that CMS include other approaches to recognizing medical homes as developed by private health plans,

some of which may not have been formally certified by an accreditation entity, within this “deeming” program.

Health Information Technology Requirements for the CCM

One of the elements of the current scope of service for CCM services that are required in order for a clinician to bill Medicare for CCM services, as finalized in the CY 2014 final rule with comment period, is the following:

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.

ACP Comment:

If this comprehensive plan is a prerequisite to billing for CCM services, the College would like to see examples of acceptable and unacceptable practices, as well as a realistic assessment of who would create such care plans and the time it would take to: do a full physical, mental, cognitive, psychosocial, functional, and environmental issues examination; plus an inventory of resources and supports; and fully take into account patient choices and values. These activities could require a multi-hour assessment to be performed properly. The College is concerned that these requirements are overly prescriptive and may make it impossible for chronic care management to work.

A care plan does not need to be comprehensive to be useful. It can be about one issue with shared decision making towards a goal – such as how and when to stop smoking. Creating a multi-page document that draws from nursing and social services potentially overburdens the plan with excessive work and verbiage. Since there are not yet any examples of the comprehensive shared care plans, such as CMS proposes, in practice at this time, it is unwise to attempt to standardize and mandate their use. It is likely that the costs will be higher and the benefits lower than CMS supposes. The key elements of a useful care plan are clarity and shared decision making.

On the other hand, a comprehensive patient-centered care plan extends beyond the requirements that CMS calls for. (See discussion below.)

In the rule, CMS states that the electronic health record for a patient receiving CCM services should include a full list of problems, medications, and medication allergies in order to inform the care plan, care coordination, and ongoing clinical care.

ACP Comment:

The College notes that patient safety requires a full list of all patient allergies, sensitivities, and intolerances – not just medication allergies. The medical community should have the opportunity to weigh in on the issue of what belongs in a medication allergy list – just IgE mediated responses – or allergies, intolerances, and preferences.

Use of Certified EHR Technology and Care Plan Requirements

In the proposed rule CMS states that requiring those who furnish CCM services to utilize electronic health record technology that has been certified by a certifying body authorized by the National Coordinator for Health Information Technology will ensure that clinicians have adequate capabilities to

allow members of the interdisciplinary care team to have immediate access to the most updated information informing the care plan. Furthermore, CMS states that requiring those that furnish CCM services to maintain and share an electronic care plan will alleviate the development of duplicative care plans or updates and the associated errors that can occur when care plans are not systematically reconciled.

ACP Comment:

While CMS and ONC have come to understand that forcing EHRs and Meaningful Use (MU) to be the same for everyone was a mistake, this proposed rule seems to call for care plans to be identical across multiple patients and clinicians. This is a very concerning approach to ACP. The potential value of a care plan is that it makes sense to the patient, was arrived at with the patient as a partner, and is realistic and actionable, as well as falling within the scope of practice of the clinician. Thus, a care plan for a sick diabetic with active foot ulcers and retinopathy should have some details and an overview by the primary care physician, and then specifics by each specialist. Beyond that, there is not sufficient evidence to support the increased volume of information and the more complex interactions called for in this proposed rule. As the MU Summary of Care measure has clearly demonstrated, more information is not necessarily of value to care providers, and may, in fact, be an impediment to safe, high quality care. The same outcome is likely if the shared care plan defined in this rule requires all care providers to share all care information related to each patient. Much of the information in the CMS-defined shared care plan will only be relevant to the author of that information.

Additionally, there is no technical specification yet to describe and support care plan reconciliation. Reconciliation should not be required until there is general agreement on what it entails and what is acceptable.

Specific EHR and Document Standards Required

CMS proposes that CCM services must be furnished with the use of an electronic health record or other health IT exchange platform that includes an electronic care plan that is accessible to all providers within the practice, including being accessible to those who are furnishing care outside of normal business hours, and that is available to be shared electronically with care team members outside of the practice. To ensure all practices have adequate capabilities to meet electronic health record requirements, the practitioner must utilize EHR technology certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170. For example, practitioners furnishing CCM services beginning in CY 2015 would be required to utilize an electronic health record certified to at least those 2014 Edition certification criteria. Given these certification criteria, EHR technology would be certified to capture data and ultimately produce summary records according to the HL7 Consolidated Clinical Document Architecture standard (C-CDA).

ACP Comment:

ACP has significant concerns with the requirements outlined above. First, the 2014 CEHRT specifications do not provide a way to share a care plan with team members who do not have access to the coordinating physician's EHR system. The best option available is to move care summaries back and forth, but this would result in movement of large documents containing mostly irrelevant information and requiring the receiver to pick around in search of care plan "fields."

Second, the version of C-CDA that is specified in the 2014 Edition certification criteria is version 1.1. However, C-CDA 1.1 does not include a care plan per se. There is no document type or section that

supports the functions needed to manage a care plan. There is a Plan of Care section, but it does not support the elements that CMS calls for, let alone all of the elements that current care management processes require. There is no element called a goal, and no way to group goals, reference or link to other elements that are expected by CMS and others.² It is not possible to connect a goal to a problem or to a care team member, as required by CMS. The reverse is also true, of course. It is impossible to determine which care team member is addressing which problem. More importantly, it is not possible to determine who is the source of each goal. There is simply no way to tell which are provider-authored goals, and which are patient authored.

Third, there are many other requirements for care plans – both data elements and functions – that cannot be supported by C-CDA 1.1. The following are CMS requirements and the concerns the College has about the ability of C-CDA 1.1 to address them:

- Congruent with patient choices and values (i.e., patient-driven goals based on shared decision making) – There are currently no appropriate data elements available, and provenance at the data element level is currently insufficient to determine the source of decisions.
- Inventory of resources and supports values – There are currently no appropriate data elements available.
- Comprehensive plan of care for all health issues – There is no way to link plans, goals or interventions to issues.
- Maintain and share an electronic care plan – 2014 certification specifications do not provide a way to share a care plan, only a care summary, which ACP believes contains much information that is extraneous and lacks much that is needed.
- Systematic reconciliation – It is not possible to systematically reconcile data that is not managed systematically.
- Available to be shared electronically with care team members outside of the practice – As noted above, 2014 certification specifications do not provide a way to share a care plan, only a care summary.

A broad variety of organizations have been studying care coordination and working to identify and implement ways to improve the process. These efforts have identified additional requirements for care plans to ensure that they provide the value needed to improve care coordination. Many of these requirements were collected and documented by the S&I Framework Transitions of Care³ and Longitudinal Coordination of care⁴ groups and HL7⁵. In order to be of any value in care coordination, all of these elements must be linked to appropriate problems, goals, resources, care team members, and members of the patient’s support team.

- Future scheduled tests and appointments
- Diagnostic tests pending
- Referrals to other care givers
- Recommended patient decision aids, clinical instructions, education materials

² The only way to state a goal in a structured way is to add a mood code called “GOL” to a Plan of Care Activity Observation. This is a work-around that developers may use to pass certification, but it no way meets the needs of clinicians.

³ <http://wiki.siframework.org/Transitions+of+Care+%28ToC%29+Initiative>

⁴ <http://wiki.siframework.org/Longitudinal+Coordination+of+Care+%28LCC%29>

⁵ http://wiki.hl7.org/index.php?title=Care_Plan

- Patient preferences, concerns, resources, supports, health status
- Interventions
- Outcomes

ACP believes that, in general, structure should be added incrementally over time. Structured data should be captured only where they are proven useful in care delivery, quality assessment, or reporting. With C-CDA it is always possible to enter the information in the Plan of Care section as plain text. The data may be there in the summary document, but it will be organized and formatted differently for each patient and each clinician. This is not a shareable format and cannot be considered an acceptable temporary substitute for doctors required to use it to qualify for the CCM payment. CMS should, instead, define a minimal set of elements and a simple structure that EHR vendors could implement as a text template. CMS should be cognizant of the differences in needs of different practices and different patient conditions and also should avoid anything approaching the complexity of the E&M documentation requirements.

Scope of Service

In the proposed rule, CMS states that it believes this scope of service element will ensure that practitioners have adequate capabilities to fully furnish CCM services, allow practitioners to innovate around the systems that they use to furnish these services, and avoid overburdening small practices. Allowing flexibility as to how providers capture, update, and share care plan information is important at this stage given the maturity of current electronic health record standards and other electronic tools in use in the market today for care planning.

ACP Comment:

ACP believes that the specifications for this scope of service element will not provide clinicians with the capabilities they need to fully furnish CCM services. Rather, this element as specified will result in additional manual effort on the part of participants and will increase the likelihood of errors and omissions, duplicative efforts, and patient harm. The only way that EPs will be able to share a care plan will be to fit a large narrative block into the plan of care element and then re-enter all of the relevant data elements as plain text. It is likely that every EP who sends a care plan in this way will structure and format it differently from every other EP. This will be a setback for interoperability and for care coordination. If any improvement in patient outcomes is detected, it will be in lieu of this requirement rather than because of its positive contribution to care coordination.

Therefore, ACP recommends that CMS offer tools that will genuinely help clinicians manage the planning of the care of their patients. CMS should wait until C-CDA version 2 has been implemented and, moreover, used successfully in the field before requiring clinicians to use it for care planning. It will be several years before we know if this is the best way to manage care plans. Criteria to measure the success of the use of C-CDA version 2 implementations should include structured data related to each of the elements specified above from the S&I Framework Transitions of Care and Long-term Care Coordination groups. Criteria should also include measures of successful outcomes related to the use of such data.

In summary, the College believes it would be a mistake for CMS to require use of a standard that does not support their own list of requirements, nor meet the requirements of clinicians coordinating care. Requiring use of inadequate technology is a patient safety issue and an unnecessary burden on all care providers. CMS should not specify this requirement at all. A future standard may meet these requirements but it is at least a couple of years away. In the meantime, physicians need guidance on

how to structure and share text care plans that are not dependent on CEHRT. There is no one best way to structure a care plan and there never will be. Also, there is no experience sharing a comprehensive patient-centered care plan outside of a single organization. We need experience in the field before we will know how to specify a particular approach. **ACP supports CCM services, other than care plans, being performed with the use of EHRs or other health IT information exchange platforms. However, having EHRs available with total interoperability 24 hours, 7 days a week is not currently possible. Therefore the College strongly recommends that CMS not require that the EHR be able to share electronic data or be accessible to all clinicians providing care during and after normal business hours.**

Clarification on Comprehensive E/M Visits

The College appreciates the change made by CMS in the final rule for 2014 that an Annual Wellness Visit (AWV) or an Initial Preventive Physical Examination (IPPE) be a requirement that a clinician furnish to a beneficiary prior to billing for chronic care management services. However, in that same rule it states “as an alternative, a practitioner who meets the practice standards that will be established to bill for chronic care management services may initiate services with an eligible beneficiary as a part of an AWV, an IPPE, or a comprehensive E/M visit”.

ACP Comment:

ACP requests further clarification as to what is meant by a comprehensive E/M visit. Does comprehensive E/M visit include any appropriate level of E/M service provided by the clinician? **ACP recommends the E/M service be any appropriate level of E/M determined by the physician at the initiation of chronic care management services.**

III. Resource-Based Practice Expense (PE) Relative Value Units (RVUs) Proposal

Using Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Rates in Developing PE RVUs

Due to a number of concerns expressed last year during the comment period, CMS did not finalize their proposal to use OPPS and ASC rates to ensure that PFS rates are based on accurate cost assumptions; however, CMS is continuing to explore alternative approaches to establishing more valid practice expense relative values units (PE RVUs). CMS has noted their continued belief that the hospital cost data (i.e., OPPS and ASC) can in some way be used in PE RVU methodology to ensure its validity. Therefore, CMS is seeking comments regarding the possible uses of the Medicare hospital outpatient cost data in potential revisions of the PFS PE methodology.

ACP Comment:

The College is not unconditionally opposed to the exploration of the use of OPPS and ASC data, which may be useful in the evaluation of supplies, site of service differentials and/or facility fees. **However, the College maintains its position of not supporting provider-based billing for care delivered in an outpatient, hospital-system owned practice when that care is not dependent on the hospital facility and its associated technologies. Rather, in line with the College’s high value care initiative, the College supports delivery of care in the most efficient setting, while maintaining quality of care.**

Although the agency has yet to make a decision on this issue, the College appreciates CMS's acknowledgement of ACP’s comments as the agency continues to look at different approaches to collecting the data on services provided in off-campus provider-based settings.

IV. Potentially Misvalued Services Under the Physician Fee Schedule

Obesity Behavioral Group Counseling – GXXX2 and GXXX3

Intensive Behavioral Therapy for Obesity has been a preventive service for patients since 2011, identified by HCPCS code G0447 (*Face-to-face behavioral counseling for obesity, 15 minutes*). Code G0447 is for individual counsel and payment. However, this type of counseling sometimes occurs in group settings, so therefore CMS is creating two new HCPCS codes for reporting and payment of obesity counseling in group settings GXXX2 (*Face-to-face behavioral counseling for obesity, group (2- 4), 30 minutes*) and GXXX3 (*Face-to-face behavioral counseling for obesity, group (5-10), 30 minutes*). The work and intensity is believed to be the same as for code G0447 which is a 15-minute code with a work RVU of 0.45. Therefore, CMS is proposing a work RVU of 0.90 for a 30 minute session to account for the longer time in the group codes. These codes will be billed on a per patient bases, therefore, the proposal describes a work RVU of 0.23 with a work time of 8 minutes for GXXX2 and a work RVU of 0.10 with a work time of 3 minutes for GXXX3. The same logic will be used for the direct practice expense and the malpractice risk factor will be cross-walked from code G0447.

ACP Comment:

ACP understands that these codes may be difficult to value for a number of reasons. However, the proposed valuation raises some concerns. First, the maximum number of potential patients in the group is used as the *typical* number of patients or average number in the group. This means that since the proposed code GXXX2 is for 2-4 patients, then the *average* number of patients would more likely be 3; whereas code GXXX3 is for 5-10 patients, thus making the average 7 or 8.

Second, grouping the whole range of patients into just two groups leads to a number of issues. For instance, providing these services for one patient is a 15 minute code, which might require 10 minutes of standard counseling with an additional 5 minutes to answer patient specific question(s). Therefore, for four patients, there might be 10 minutes of standard counseling as well, but then 5 minutes per patient to answer their individual questions—this equates to 30 minutes. And when these services are provided for ten patients, the time is more likely to be 60 minutes. Therefore, in the proposed valuation, code GXXX3 would be undervalued by only allowing 30 minutes for those services.

The proposed valuations of the codes are as follows:

# of patients	RVU	Time
1	0.45	15
2	0.46	16
3	0.69	24
4	0.92	32
5	0.50	15
6	0.60	18
7	0.70	21
8	0.80	24
9	0.90	27
10	1.00	30

This valuation presents an uncomfortable rank order anomaly. Counseling four patients is valued more (and theoretically takes more time) than counseling six, seven, eight or nine patients. Counseling four patients is valued almost twice that of counseling five patients.

Therefore, ACP recommends the following options for CMS' consideration:

Method 1: Conclude that a group of 5-10 patients will require 60 minutes with a total RVU of 1.8. Therefore, based on 10 patients, each RVU per patient is 0.18 and time per patient is 6 minutes.

This would lead to the following:

# of patients	RVU	Time
1	0.45	15
2	0.46	16
3	0.69	24
4	0.92	32
5	0.90	30
6	1.08	36
7	1.26	42
8	1.44	48
9	1.62	54
10	1.80	60

With this method, there is still a savings in scaling up the number of people in the group. 10 patients in a group is valued the same as 4 patients performed individually.

Method 2: Another potential solution would be to create the codes as add-ons, similar to the cryotherapy codes. In that case, you would have the base code of 0.45 RVU with 15 minutes, and then an add-on code for each additional patient, of say 5 minutes with RVU of 0.15. That would still keep the work intensity the same throughout the family. In this scenario, four patients would be valued at 0.90 and 30 minutes of time. 10 patients would be valued at 1.8 RVUs with time of 60. In this scenario, there are no rank order anomalies. In both methods four patients takes about 30 minutes and 10 patients take about 60 minutes.

V. Concerns with the 10- and 90- Day Global Packages

In the proposed rule, CMS outlines a number of frequent and noteworthy concerns about the accuracy of the 10- and 90-day surgical global codes, and thus proposes to transition all 10- and 90- day global codes to 0-day global codes; with 10-day global codes transitioning in CY 2017 and 90-day global codes transitioning in CY 2018.

ACP Comment:

ACP agrees with and supports the agency's decision to transition all 10- and 90- day global codes to 0-day global codes.

ACP has noted that global payments are supported by CMS as evidenced by their use in the hospital inpatient and outpatient prospective payment systems. ACP agrees with CMS that the RUC

recommendations are an essential element that is considered when valuing a code. Therefore, ACP believes it would be advantageous for RUC and CMS to work collaboratively to explore the available appropriate group practice data and CMS data to validate the actual number of post-operative visits. CMS, along with the RUC, could also review the Medicare Part A claims data to determine the length of stay of surgical services performed in the hospital facility setting. Matching the average length of stay with the post-operative visits in the physician time file would provide the opportunity to identify anomalies within the data set that could be further reviewed. The RUC, working along with CMS, could review post-operative visit length of stay data for outliers.

ACP recognizes that the codes with very low and negative intra-service work per unit of time (IWPUTs) would have to be surveyed as directed by CMS instruction to the RUC that this be performed. Rasch pairings would be an acceptable methodology for surveying large numbers of codes in a family, perhaps supplemented by a standard survey of several "anchor" codes, to establish the work RVUs.

VI. Valuing New, Revised, and Potentially Misvalued Codes

ACP applauds CMS for their proposal to provide additional transparency and comment opportunity in the valuation of physician and other healthcare professional services. CMS proposes to modify this process by proposing that all changes in the work and Malpractice (MP) RVUs and the direct PE inputs for new, revised and potentially misvalued services under the PFS be included in the proposed rule, beginning with the PFS proposed rule for CY 2016. CMS would include proposed values for all new, revised, and potentially misvalued codes for which they have complete RUC recommendations by January 15th of the preceding year.

Additionally, as part of this proposal, CMS has indicated they would eliminate the Multi-Specialty Refinement Panel process currently used to consider comments on interim relative values.

ACP Comment:

Given the incongruity between the CPT/RUC workflow and the CMS proposal, ACP notes the need for both to be adjusted in order to accommodate publication of the maximum number of code values in the Proposed Rule. **ACP recommends that CMS not make January 15 of each year the required deadline for submitting RUC recommendations to be included in the following year's Medicare Physician Fee Schedule. Additionally, ACP recommends retaining the current CPT/RUC meeting infrastructure, while shifting the workflow of the meetings in order to accommodate the Agency's rulemaking process. ACP further recommends that the CMS wait to begin implementing the new timeline until the 2017 Medicare Physician Fee Schedule.** The CMS recommended implementation date of 2016 is premature as it would have a serious impact on the development of new technology and new code bundles which are already underway for the CPT® 2016 code set. ACP, along with 70 other organizations, has signed on to the American Medical Association's (AMA) alternative to the proposal outlined in the Proposed Rule for the 2015 Medicare Physician Fee Schedule, and supports the recommendations listed therein.⁶

Historically, ACP physician members have served in an advisory capacity to the Multi-Specialty Refinement Panel; providing an independent and unbiased primary care provider voice to the process. ACP has concerns with the elimination of this panel and solely relying on agency staff to determine if the comment is persuasive in modifying a proposed rule.

⁶ The letter can be accessed here: http://www.acponline.org/acp_policy/letters/ruc_and_cpt_timeline_2014.pdf

VII. Removal of Employment Requirements for Services Furnished “Incident to” Rural Health Clinics (RHC) and Federally Qualified Health Center (FQHC) Visits

CMS proposes to change current regulations which state that services furnished “incident to” an RHC or FQHC visit must be furnished by an employee of the RHC or FQHC. This is a burden on physicians because staff that does not fit this description cannot bill Medicare directly and receive payment. The agency proposes to remove this “incident to” requirement.

ACP Comment:

ACP recognizes the staffing difficulties that physicians in RHCs and FQHCs face and applauds CMS’ proposal to allow as much flexibility as possible with their staffing needs. ACP strongly supports and applauds the agency’s proposal to expand the capacity of nurses, medical assistants, and other auxiliary personnel by allowing them to furnish “incident to” services under contract in RHCs and FQHCs.

VIII. Reports of Payments or Transfers of Value to Covered Recipients (Proposed Changes to the Open Payments Program)

The College is supportive of the Open Payments Program and its goal of increased transparency regarding industry, and physician and teaching hospital financial (value) relationships. We believe this program and similar transparency efforts by CMS can decrease inappropriate conflicts of interest, improve beneficiary decision-making, and reinforce an atmosphere of trust between physician and patient—this openness is at the core of our members’ commitment to ethical and professional behavior.

The current Open Payments regulations include an exception to the reporting requirements for specified continuing education arrangements. More specifically, Section 403.904(g)(1) of the current open payments regulation states that payments or other transfers of value provided as compensation for speaking at a continuing education program need not be reported if all of the following three conditions are met:

- The event at which the covered recipient is speaking must meet the accreditation or certification requirements and standards for continuing education for one of the following organizations: the Accreditation Council for Continuing Medical Education (ACCME); the American Academy of Family Physicians (AAFP); the American Dental Association’s Continuing Education Recognition Program (ADA CERP); the American Medical Association (AMA); or the American Osteopathic Association (AOA);
- The applicable manufacturer does not pay the covered recipient speaker directly; and
- The applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program.

CMS states in the proposed rule that, “industry support for accredited or certified continuing education is a unique relationship” and attempts to maintain the reporting exclusion for industry subsidized speaker/faculty payment under Section 403.904(i)1 in which the industry funder does not know the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year. However, the proposed rule would add additional exclusion criteria that would apply if the industry funder of the continuing education event does not either:

- select or pay the covered recipient speaker directly, or;

- provide the continuing education provider with a distinct, identifiable set of covered recipients to be considered as speakers for the continuing education program.

In these cases, CMS would consider these payments excluded from reporting.

ACP Comment:

The College has significant concerns regarding the proposed change to modify the reporting exclusion for speakers or faculty involved in a continuing education event that is supported by industry. We recognize that the intent of the change is NOT to remove the reporting exclusion for such speaker/faculty payments, but to prevent the unintended appearance of CMS endorsing specific continuing education sponsors above others, to increase consistency in reporting, and to eliminate the redundancy of this exception with another exclusion in the regulations (Section 403.904(i)1), which, as noted earlier, excludes indirect payments or other transfers of value where the applicable manufacturer is “unaware” of the identity of the covered recipient.

The College believes the solution being proposed by CMS is inadequate—it is both overly stringent and not stringent enough at the same time.

- The solution is overly stringent in that the expectation that the industry funder will not be able to identify the set of covered recipients for the defined period of time is unrealistic—it is very likely that industry could learn the identities of speakers/faculty and potentially participants after funds have been transferred and the event has occurred through brochures, programs, and other publications, or through their physician-employees’ participation in continuing education activities (either as speakers/faculty or attendees). Also, the uncertainty regarding whether an event will qualify under this exclusion as a result of this unrealistic criterion would likely have an adverse impact on participation of covered recipients within these events.
- The proposed solution is not stringent enough in that it appears to provide “loop-holes” for industry sponsors to have undue influence on the event. For example, there is no prohibition against the industry sponsor having influence on event planning or the content of the event. This type of prohibition is present under the current rule, in that it is a standard requirement of the accreditation/certification organizations listed. The proposed modification also does not provide any third-party validation that the exclusion criteria are being met.

If CMS desires to continue the exclusion of certain continuing educational activities from the Open Payments reporting requirement, the College strongly encourages an approach that truly minimizes industry influence in the situation. To do otherwise defeats the transparency goal of this program. **Thus, the College suggests that CMS either:**

- **withdraws the current proposed modification and maintains the current approach that provides a clear standard for approval and offers reasonable protections from undue industry influence, or**
- **implements an alternative approach , briefly discussed in the proposed rule, in which CMS develops a list of standards (criteria) required for the reporting exclusion that ensures the independence of the continuing education activities such as the Standards for Commercial Support: Standards to Ensure Independence in CME Activities used by the Accreditation Council for Continuing Medical Education (available at <http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>. The process to verify satisfaction of these standards could consist of**

an attestation and sample audit, internal evaluation directly by CMS or the establishment of a deeming approach. This alternative approach would allow a wider variety of continuing education sponsors to offer activities excluded from “Open Payment” reporting, while also providing the necessary protections from undue industry influence. This approach would also provide the needed certainty to attendees that the event offered by accredited/certified entity meets the exclusion criteria.

IX. Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models

CMS proposes to exercise their authority under the Innovation Center legislation and regulations to obtain access to identifiable data from patients, physicians and other health professionals, and suppliers that are participating in an Innovation Center program. Identification of data at the individual level is necessary for a variety of purposes, including the construction of control groups and to effectively evaluate such factors as outcomes, clinical quality, adverse effects, access, utilization, patient and provider satisfaction, sustainability, and total cost of care.

ACP Comment:

ACP supports the activities of the CMS Innovation Center and recognizes its need to access identifiable data from participants in their programs to conduct meaningful evaluations. The College encourages CMS to make any additional data reporting that may be required by program participants through this regulatory change to be as minimally burdensome as possible and to provide participants with adequate instruction and education resources to ensure that collection and data reporting complies with HIPAA Privacy and Security Rules. The College further appreciates that this identifiable data will be protected under CMS’ Acceptable Risk Safe Guards guidelines, that data exchanges will meet all E-Gov guidelines and that the identifiable data will be deleted when the evaluation is complete and all necessary policy deliberations have been finalized.

X. Medicare Shared Savings Program

CMS is proposing to make the following changes to the Medicare Shared Savings Program: to modify the current set of quality measures; to modify the current quality performance benchmark methodology, including the timeframe between updates to the benchmarks; and to establish an additional incentive to reward ACO quality improvement each year

ACP Comment:

The College generally supports the proposed changes in the Medicare Shared Savings Program (MSSP). More specifically,

- ACP commends CMS for its efforts to improve quality reporting under the MSSP through eliminating duplicative measures, transitioning from process to outcome measures, attempting to align measures with other federal quality healthcare programs, and reducing the burden of reporting through the increased use of measures that do not require direct reporting by the participating MSSP entity, and reducing the minimal MSSP PQRS reporting requirement.
- The College supports the proposed additions and eliminations to the current set of quality measures with the following exceptions and concerns:
 - **The College suggests that the proposed “All-Cause Unplanned Admissions for Patients with Diabetes Mellitus (DM), Heart Failure (HF) and Multiple Chronic Conditions” measures are underdeveloped and could benefit from further modification to improve**

- clarity and reliability.** In addition, the HF measure appears to overlap significantly with current measure ACO-10, “Ambulatory Sensitive Conditions Admissions: Heart Failure”.
- **The College, while in support of adding mental health measures, is concerned that the “Depression Remission at Twelve Months” measure may be burdensome to obtain and reflect a standard that is too difficult to meet**—this is particularly problematic in rural/low SES settings.
 - The College, while recognizing the importance of patient experience of care measures, questions the appropriateness of the proposed “Stewardship of Patient Resources” measure, which assesses whether the patient recalls any discussion of the cost of medications prescribed. Such discussions, while appropriate for “high tier”, costly medications, are of questionable value relative to measuring patient-centered, quality care delivery for more frequently prescribed, lower cost, generic medications. **Since the proposed measure does not differentiate between these categories, the College believes it should be removed or significantly modified to reflect this distinction.**
 - The College is concerned that risk adjustment methodology being employed under ACO quality measurements efforts remains less than optimal. We are encouraged by the recent work reported in the MedPAC June 2014 “Report to Congress” that recognizes significant limitations in currently used risk adjustment procedures and outlines a plan of action towards improvements.
 - The College supports CMS’ efforts to
 - increase benchmark stability through lengthening the update period to 2 years, and
 - to remove adverse biases in the benchmarks related to “topped-out” measures, and to MSSP programs either located in low-cost geographic areas or that have been significantly successful in lowering healthcare costs during their first 3-year contract within the program.
 - The College also supports CMS’ proposal to enhance its current quality scoring strategy by explicitly recognizing and rewarding MSSPs that make year-to-year improvements in their quality performance. This addition is consistent with the “Joint Principles for Accountable Care Organizations” endorsed by ACP and the other major primary care medical organizations, which is available at: http://www.acponline.org/acp_policy/policies/joint_principles_accountable_care_organizations_2010.pdf. The College, while in full support of the addition of an improvement incentive, does question whether the maximum number of bonus points available under the proposal adequately recognizes this important dimension of improvement. **Thus, we are suggesting that CMS consider increasing the number of potential bonus points (e.g. to 4 per domain) that can be earned.**

Additionally, the College, while recognizing that this issue was not specifically addressed in the proposed rule, again requests that CMS make necessary changes to the MSSP attribution methodology to remove “ACO exclusivity” from non-primary care specialty physicians.

XI. Physician Compare

In the proposed rule CMS continues the phased in approach to developing the Physician Compare website to include information on physicians and eligible professionals enrolled in the Medicare program. CMS proposes to make a broader set of quality measures, both individually reported measures and group reported measures, available for publication on the website.

CMS also is considering creating composites using 2015 data and publishing composite scores in 2016 by grouping measures based on the PQRS GPRO measure groups, if technically feasible. These groups could include Care Coordination/Patient Safety (CARE) measures, Coronary Artery Disease (CAD) Disease Module, Diabetes Mellitus (DM) Disease Module, and Preventive (PREV) Care measures. Consumers have requested this type of information as a way for patients to better understand quality measure data. CMS plans to analyze the data to determine if this is feasible, but requests feedback on this approach.

CMS also seeks comment on including specialty society measures on Physician Compare. For example, CMS seeks comment on the option of linking from Physician Compare to specialty society websites that publish non-PQRS measures.

ACP Comment:

The College supports the overall goals of the Physician Compare Website and supports efforts to improve transparency in the health care system. Transparent health care information is useful for a wide range of stakeholders, and can help patients and their families make more informed health care choices. The College supports alignment with the PQRS reporting and using nationally recognized performance measures and data collection methodology in the Physician Compare Website. In addition, the College is generally supportive of CMS' proposal to display all PQRS measures collected in 2015 in 2016. Furthermore, ACP supports increased efforts to determine and employ the most effective means of presenting performance information to patients/consumers and to educate these information users on the meaning of performance differences among clinicians, and on how to use this information effectively in making informed healthcare choices. **Therefore, ACP is supportive of the proposal to have all measures be available for download and to only include a select group of measures on the webpage. ACP supports working with consumer groups to identify the meaningful measures for consumers and encourages CMS to ensure that measures on the webpage remain patient centered and reflect potential differences in risk/benefit for specific populations.** ACP appreciates the 30-day preview period prior to publication of quality data on Physician Compare so eligible professionals, groups, and ACOs can review their data prior to public reporting. **The College emphasizes the importance of physicians and other health care professionals having timely access to performance information prior to public reporting and a fair chance to examine and appeal potential inaccuracies.** In addition, the College urges CMS to engage in significant outreach prior to publicly reporting data to ensure that physicians are able to have sufficient time to review, validate, and appeal their data. CMS should monitor the impact of this preview period and consider extending the 30-day preview period if physicians are unable to access and review their information. ACP would be supportive of CMS calculating composite scores for measures as they often are easier for consumers to understand and give a broader picture of clinical quality. ACP encourages CMS to be transparent on the methodology used to calculate these scores and ensure that scores are accurately and appropriately risk adjusted. If CMS decides to include specialty society measures on physician compare, ACP encourages CMS to ensure that the measures have a strong evidence base, are vetted externally, and include a description of how the measure differs from PQRS measures.

XII. Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System Changes to Reporting Requirements

CMS proposes changes to the criteria for satisfactory reporting for PQRS based on method and group size. The proposed reporting requirements are largely in line with the 2014 PQRS payment incentive reporting requirements. Proposed changes include increasing the number of measures required,

covering National Quality Strategy (NQS) domains, and the inclusion of outcome-based measures (for the clinical quality data registry). CMS also seeks feedback on whether to propose in future rulemaking to allow more frequent submissions of data, such as quarterly or year-round submissions, rather than annually.

Individual Reporting

Individuals reporting via claims and registry would be required to report at least 9 measures, covering at least 3 NQS domains for at least 50% of the EPs to which the measure applies. CMS is also proposing a new requirement that if an EP sees at least 1 Medicare patient in a face to face encounter, they would report on at least 2 cross-cutting measures from the set specified in Table 21. Individuals reporting via a certified EHR would report 9 measures covering at least 3 NQS domains. In addition, CMS is proposing to have the EP or group practice provide the CMS EHR Certification Number of the product used by the EP or group practice for direct EHRs and EHR data submission vendors. For measure groups, individuals would need to report at least 1 measure group for at least 20 patients (majority must be Medicare patients). Lastly individuals could report via a qualified clinical data registry (QCDR). QCDR participating EPs would report at least 9 measures covering at least 3 NQS domains for 50% of the EP's patients. In addition, CMS is proposing to require that at least 3 of the QCDR reported measures must be outcome measures. If there are not 3 applicable outcome measure, CMS is proposing to submit measures related to resource use, patient experience of care, or efficient/appropriate use.

Group Reporting

CMS is proposing to change the deadline by which a group practice must register to participate in GPRO to June 30, instead of September 30. In addition, CMS proposes to increase the number of required measures for successful reporting. Group practices using a qualified registry or EHR reporting would report on at least 9 measures covering at least 3 NQS domains. CMS is also proposing a new requirement that if a group sees at least 1 Medicare patient in a face to face encounter, they would report on at least 2 cross-cutting measures from the set specified in Table 21. CMS is also proposing to require groups of 100 or more EPs to report Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey measures. These measures would be collected through a certified vendor. CMS is also proposing to require that beginning with the reporting period for 2018 PQRs payment adjustment, groups of 25 or more EPs that are participating in GPRO report and pay for the collection of CAHPS for PQRs survey measures.

ACP Comment:

ACP appreciates CMS' focus on aligning requirements with other quality reporting programs, such as Medicare EHR Incentive Program, Physician Value-Based Payment Modifier, and the Medicare Shared Savings Program. The College has long supported quality improvement, both through quality measurement and reporting. ACP supports the use of structure, process, and outcome measures in programs and is encouraged by their inclusion in the PQRs program. However, the College remains concerned that the measures and reporting periods within the PQRs program continue to be unaligned with other reporting programs such as meaningful use and maintenance of certification (MOC) requirements. **The College continues to encourage CMS to improve alignment among quality improvement programs and reporting systems to decrease burden on physician practices.**

The College appreciates CMS exploring ways to provide more timely feedback to physicians and would be supportive of giving physicians and practices the option to report more frequently throughout the reporting year. Allowing practices the option to report more often would be beneficial especially for those practices working on quality improvement and are experienced with the reporting requirements.

The College would not support making more frequent reporting mandatory as many practices are still new to the reporting requirements.

ACP supports measuring patient care experiences. Since the cost to administer the survey will be at the practice's expense, ACP is concerned that CMS is requiring this for practices of 100 or more. In addition, the College is concerned if this requirement is expanded to smaller practices as this would have a significant financial impact on the practice to administer the survey.

In regards to EHR reporting for both individuals and groups, the College understands CMS' proposal to provide the CMS EHR Certification Number of the product and believes this will have a minimal impact on physicians and their practices. EPs must provide this ID when they attest for Meaningful Use; therefore, the College believes this will only result in minimal additional effort and further aligns requirements among federal programs. **ACP encourages CMS to monitor and work with the EHR vendor community to ensure that the EHR vendors are able to report a large number of measures, as recently many of the certified systems have cut back on the number of measures that they support.** In addition, EPs who chose to report via a certified EHR are limited to the list of measures that their particular system supports. EPs should be able to select measures from those available in their system, and if they are unable to meet the PQRS reporting requirements with the measures available, then the EPs should not be penalized.

Proposed PQRS Measures Updates and Changes

CMS is proposing adding 28 measures for individual reporting and 4 new measure groups. In addition, CMS proposes to remove 73 measures from the PQRS program.

ACP Comment:

ACP supports CMS' proposal to remove measures with or near 100% adherence, duplicative measures, and measures that no longer reflect current guidelines.

XIII. Value-Based Payment Modifier and Physician Feedback Program

Through this proposed rule CMS is concluding the phased in approach of the value-based payment (VBP) program. CMS is proposing to apply the value modifier (VM) to all physicians and groups of physicians and also non-physician eligible professionals and to increase the amount of payment at risk from 2% to 4.0% in CY 2017 and each subsequent calendar year payment adjustment period. CMS is also proposing to apply the VM to physicians and non-physician eligible professionals participating in the Shared Savings Program, the Pioneer ACO Model, the CPC Initiative, or other similar CMMI or CMS initiatives starting in CY 2017. In general, the cost composite for ACO participant TINs that participate in the Shared Savings Program during the payment adjustment period would be classified as "average cost" and their quality composite would be based on the ACO's quality data from the performance period using the quality-tiering methodology.

ACP Comment:

ACP supports transitioning our health care system to a value-based payment approach, rather than a volume-based payment system. The College believes that a new value-based system should facilitate coordinated, comprehensive, longitudinal care provided by physicians working in collaboration with other health care professionals. ACP recognizes that CMS is required by law to apply the value modifier to all physicians in 2017. **Due to continuing low participation rates in PQRS among physicians and non-**

physician EPs⁷, ACP strongly recommends that CMS use the next year to engage in outreach to all practices to encourage them to participate in the PQRS program and work to increase PQRS participation rates. ACP encourages CMS to continue engaging with specialty societies in education outreach but also explore new opportunities such as working with the local Medicare Administrative Contractors (MACs) to ensure that those new to the program are aware of the requirements and penalties. In addition, CMS needs to ensure that practices, especially solo and groups with 2-9 EPs are:

- Aware of the value based payment program
- Aware of the alignment of the value based payment program with PQRS reporting
- Able to understand what the value based payment program involves and how it will impact them; and
- Able to provide meaningful feedback to CMS throughout the implementation of the value based payment program.

In addition, the College does not support the increased payment at risk from 2% to 4%. Physicians and eligible professionals are facing a large amount of penalties in the future (an upwards of 9% in 2017 based on PQRS, VBP, and Meaningful Use requirements) and many EPs will be new to the PQRS program and the VBP program. In addition, due to the changes every year in the requirements for these programs many physicians find it challenging to keep up and ensure they are doing the necessary work to meet the new requirements. The College encourages CMS to reduce variation in the programs from year to year to give physicians the opportunity to learn how the program works and how the programs affect their practice before increasing the financial penalties yet again.

Two-Category Approach

As in previous years of the VBP program, CMS proposes to use a similar two category approach based on participation in PQRS. Category 1 would include groups that meet the criteria for satisfactory reporting of data on PQRS via GPRO and groups that have at least 50% of their EPs meet the criteria for satisfactory reporting of data on PQRS as individual reporters or in lieu of satisfactory reporting participate in a PQRS qualified clinical data registry. Category 1 would also include solo practitioners that meet the criteria for satisfactory reporting or in lieu of satisfactory reporting participate in a PQRS qualified clinical data registry. Category 2 would include all other groups or solo practitioners and would be subject to a -4.0% adjustment (this would be in addition to the -2% under the PQRS reporting requirements).

ACP Comment:

The College appreciates the proposal to allow group practices to satisfy the VBP requirement by having 50% of the group's EPs report PQRS as individuals. This will be especially helpful to smaller groups that do not have the experience with or have not used the group reporting option for PQRS in the past. This approach continues CMS' goal of increasing quality reporting and does not apply restrictions on how a group must report, allowing groups to choose an option that best fits their practice.

Quality-Tiering

CMS proposes to make quality-tiering mandatory for groups and solo practitioners within Category 1 for CY 2017. Groups 2-9 and solo practitioners would be held harmless from downward adjustment and would only be subject to neutral or upwards adjustment as this is their first year in the program. Groups

⁷ 2012 Physician Quality Reporting System (PQRS) and Electronic Prescribing (eRx) Experience Report. Accessed online at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/AnalysisAndPayment.html>

with 10 or more EPs would be subject to upward, neutral, or downward adjustments determined under quality-tiering. Based on analysis from CY 2012 claims, CMS estimates that approximately 6 percent of all EPs are in a Category 1 TIN that would be classified in tiers that would earn an upward adjustment, approximately 11 percent would receive downward adjustment, and 83 percent would receive no payment adjustment. In addition, CMS proposes to increase the amount at risk from 2.0% to 4.0% in CY2017.

ACP Comment:

The College believes this is a reasonable approach for CMS to pursue and appreciates the proposal for only upward or neutral adjustments for those clinicians or groups that are new to the VBP program. Allowing solo EPs and groups of 2-9 EPs to avoid risk for a downward adjustment is an appropriate extension of implementing the VBP program and will allow these groups to gain experience before being at risk for a downward adjustment.

However, as noted earlier, the College is not supportive of the proposal to increase the amount of payment at risk from 2.0 percent to 4.0 percent in CY 2017. As CMS notes, the law does not specify the amount of payment that should be subject to the adjustment. Since CMS and physicians lack any experience with the program, as 2015 will be the first year that the VM is applied to physician groups, ACP encourages CMS to fully implement and evaluate the program before increasing the potential penalty. **As proposed, a 4 percent reduction would be applied to groups that fall into Category 2. This would be in addition to the PQRS 2 percent reduction and would likely have a significant impact on all practices, especially small ones. As noted earlier, the 2012 PQRS participation rates remain low and the College is concerned about the combined 6.0 percent penalty that practices would face in CY 2017.** ACP encourages CMS to refrain from making any changes to the amount of payment at risk at this time.

Quality & Cost Measures

CMS' proposals for the quality and cost measures are the same as used in the 2016 program year. CMS is proposing to use the same quality measures reported via PQRS in the VBP program, the total per capita cost measure, total per capita costs for beneficiaries with four chronic conditions (COPD, Heart Failure, Coronary Artery Disease, and Diabetes), and the Medicare Spending per Beneficiary measure. In addition, in line with the proposed PQRS requirements, groups of 100 or more EPs are required to use the CAHPS measures. In addition, CMS proposes to continue to use the same specialty adjustment group cost methodology used in the 2016 program.

ACP Comment:

ACP appreciates the alignment between the PQRS and VBP program. **In addition, ACP encourages CMS to explore appropriate ways to adjust quality and cost scores for socioeconomic status and location of care to ensure accurate physician-to-physician comparison groups.**

Informal Review Process

CMS proposes a new informal review process for the VBP program when a physician or group practice believes CMS has erred in calculating the VBP composites. For the 2015 adjustment (which is based on 2013 reporting for groups of 100 or more), CMS proposes to allow groups to submit a request by January 31, 2015. If CMS is found to be incorrect for the 2015 adjustment, groups would be reclassified as "Average Quality" for an error in the quality composite and CMS would recalculate the cost composite. For the 2016 adjustment and beyond, CMS is proposing to have physicians and their practice submit a request by 30 days after the Quality and Resource Use Reports (QRURs or Physician Feedback

reports) are disseminated. For 2015 adjustments and beyond, CMS would recalculate both the quality and cost composites.

ACP Comment:

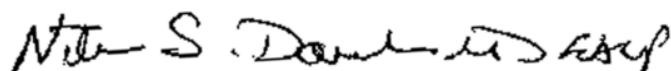
ACP appreciates CMS developing this informal review process to allow physicians a clear avenue to address issues found within the VBP program. ACP is concerned with the short window of 30 days after the QRURs are disseminated as proposed in 2016 and beyond. Anecdotally, download rates of the QRUR reports continue to be low and ACP encourages CMS to expand this time frame. The College understands CMS' desire to address all issues before applying the VM to avoid having to re-process claims during the year which the modifier is applied. However, ACP does not think that 30 days is an adequate amount of time for physicians and their practices to become aware of the report being available, download the report, and review for accuracy.

ACP urges CMS to engage in significant outreach to physicians, group practices, specialty societies, etc. when the reports are available for downloading. Working with specialty societies and/or state MACs could help spread the message to a broad group of physicians, giving physicians adequate time to review the report before the review period (30 days as proposed) lapses. Furthermore, as CMS explores ways to provide more frequent and timely feedback to physicians on their performance data, ACP encourages CMS to allow physicians and other health care professionals to have access to prior years' performance data at any time so they are able to make comparisons and quality improvement changes in their practices.

In conclusion, ACP would like to reiterate our appreciation of the effort that CMS is making to reform the Medicare Physician Fee Schedule. However, we strongly urge CMS to step back and review the physician fee schedule as a whole rather than just as individual components. It is tremendously difficult for physicians to know what exactly to do to address the constantly changing requirements that CMS and other payers ask of them—and if they determine what to do, then they must find the time to carry it out while still providing high quality care to their patients and managing the other day-to-day activities and business aspects of their practice.

Thank you for considering ACP's comments. Please contact Shari M. Erickson, MPH, Vice President, Governmental Affairs and Medical Practice, by phone at 202-261-4551 or e-mail at serickson@acponline.org if you have questions or need additional information.

Sincerely,



Nitin S. Damle, MD, FACP
Chair, Medical Practice and Quality Committee