



June 2, 2011

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Re: Medicare Shared Savings Program: Accountable Care Organizations (CMS-1345-P)

The American College of Physicians (ACP), consisting of 130,000 internal medicine physician specialists and student members, appreciates this opportunity to comment on the *Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations and Medicare Program: Waiver Designs in Connection With the Medicare Shared Savings Program and the Innovation Center; Proposed Rule and Notice*

Overall Comments

The ACP strongly supports the intent of the proposed rule, and believes that an ACO model has the *potential* of supporting such important care delivery goals as enhancing quality, efficiency, integration, and patient-centeredness. The College is also pleased that the foundation of care under this payment model, as reflected in the proposed rule, is primary care. There is substantial research evidence derived from both domestic and international settings that a strong primary care foundation is the essence of an effective and efficient healthcare system.

We are concerned, though, that the current requirements proposed for acceptance as an ACO by Medicare under this program sets too high of a bar for participation by many internal medicine physicians, especially internal medicine specialists in primary and comprehensive care of adults who practice in smaller, independent physician practices. The required administrative, infrastructure, service delivery, and financial resources and the need to accept risk will effectively limit participation to those few large entities already organized under an ACO-like structure; that already have ready access to capital, substantial infrastructure development, and experience operating under an integrative service/payment model (e.g. Medicare Advantage). Even these entities have questioned the “business case” for adoption of the ACO model as outlined in the proposed rule. We do believe that the Center for Medicare and

Medicaid Innovation's (CMMI) recent release of the Pioneer option, with its increased administrative flexibility and ability to earn a higher share of savings than allowed in the proposed rule, may effectively address this issue for the larger, already prepared players. We also are intrigued by the proposal from CMMI for an "advance payment" initiative for ACOs participating in the Medicare Shared Savings Program, which may be attractive to ACOs organized around smaller practices, and will be providing separate comments on this option.

We believe there are a substantial number of physician practice collaborations of varying size, particularly those already providing primary care services that have achieved or are prepared to achieve recognition as qualified Patient-Centered Medical Homes, that would now or in the near future be interested in exploring the possibility of partnering with CMS within a shared saving payment structure; but the current requirements make such a consideration impractical. This is unfortunate. It is the hope of ACP that through suggested changes within the proposed rule, and/or through new initiatives through the CMMI, there will be an increased opportunity for a wider scope of physician practices to participate under the new payment model.

To address this shortcoming, the College recommends that CMS create a pathway for practices of varying sizes and level of practice transformation to participate in ACOs. We envision the development by CMS of a pathway to care delivery and payment within an accountable care structure, with a "ladder" of entrance levels where the amount of potential financial reward (i.e. percentage of shared savings) is linked to the service, quality, and risk assumption requirements the collaborate entity chooses to accept. Such a pathway would be much broader than the two participation options outlined in the proposed rule. It would provide an opportunity for collaborating practices to enter at a reasonably low level of expectation and obligation, with higher available incentives to encourage their development further up the "ladder" of increased achievement toward the model's goals. It is similar in concept to how the PCMH care and payment model was introduced into practice; where practices could be recognized at three levels of PCMH achievement and payments (e.g. monthly care coordination fees), which increase with increasing levels of recognition.

The College acknowledges that the new Shared Savings/ACO option is just one of many potential approaches (e.g. PCMH, Risk Adjusted Comprehensive Payment, partial and total capitation, Prometheus Episode Payment) that can promote care aligned with the three aims of improving the experience of care, improving the health of populations, and reducing per capita costs of health care. We further believe that many physician practices will appropriately choose not to participate under this ACO model at this time. However, if CMS were to allow a more diverse group of practices to explore, apply, and start on the road toward full ACO development, a larger portion of Medicare beneficiaries will have access to the improved quality, efficiency, integration, and patient-centeredness promoted by this approach. By maintaining entrance requirements only obtainable by "elite" entities, there is a missed opportunity to leverage the benefits of this approach throughout the care system.

The following are specific recommendations regarding the proposed rule that follow from the global perspective outlined above and are intended to improve program implementation:

Shared Savings Model Options—The proposed rule offers participants two shared savings options; a one-side option that accrues no financial risk until year three of the contract, and a two-side option that accrues risks in all three years of the contract. The amount of potential financial gains (i.e. percentage of shared savings available) is appropriately linked to the amount of risk assumed. **Consistent with the perspective outlined at the beginning of this comment letter, the ACP encourages CMS to add a third option—a true up-side only option, which is consistent with the language in the establishing legislation, where participating entities will be able to share in any saving compared to the established benchmark, but will not be expected to share in any losses compared to that same benchmark.** Note that calling this an “up-side only” option is a misnomer, since it doesn’t recognize the substantial upfront start-up and increased first-year operating costs that the ACO entity must expend to participate within the program. It is our belief that by adding this option, an increasing number of physician practice collaborations (e.g. Independent Practice Associations, single and multi-specialty practices, regional collaborations among independent practices), many of which have limited access to capital and limited experience with risk contracting, would be more willing to explore and potentially participate within the program. This would be particularly true for collaborations developed among small- and medium-size primary care practices.

If CMS is agreeable to provide a third up-side only option, but would like to focus its availability, the College offers the following alternative recommendation. CMS could limit entry to this shared savings up-side option solely to those ACO applicants that qualify for the proposed exemption to the 2 percent net savings threshold — these are collaborations with less than 10,000 beneficiaries assigned that must meet one of four requirements set in the proposed rule, which includes ACOs composed only of professionals in group practice arrangements or networks of individual practices of ACO professionals. This would tend to focus the option on collaborations of small- and medium-size practices.

Higher Shares of Savings for ACOs—The potential amount of shared savings available to participating ACOs reflected in the proposed rule makes the business case for participation generally unattractive. This is particularly true for the participation of collaborations among small and medium size practices. The significant upfront and operating costs required for participation, in addition to the potential for losses and the required withhold significantly outweighs the potential for gains and results in a barrier to participation. The problem is further highlighted by the fact that the ACO will not receive any portion of earned shared savings for almost a year after the savings are actually achieved. **In order to address this issue and encourage increased participation within the ACO program, the ACP believes that the percentage of shared savings that the ACO can receive must be increased under all options. This potential to earn an increased percentage of shared savings would be most important in the initial years of the ACO’s participation in the program.**

Quality Measures—**The College strongly supports CMS’ decision to link shared savings to the degree that defined quality measures are achieved but has concerns about the large number of measures that ACOs would be required to report on.** We agree that reporting on quality measures is important to avoid the perceived or actual obtaining of savings from providing care of lesser quality. In addition, the College commends CMS for primarily employing measures approved through the multi-stakeholder National Quality Forum (NQF)

consensus-development process and/or aligned with the measures in other CMS programs such as the Electronic Health Records (i.e. HITECH), Physician Quality Reporting System (PQRS), and E-Prescribing Incentive programs. The College also appreciates the proposed option to allow ACOs to qualify for the PQRS incentive on behalf of all its participants—an option that can help lessen an administrative burden for the participating providers. The College has two primary concerns regarding the quality measurement aspects of the proposed rule:

- **The large number of measures required to be reported would be a significant operational obligation that would serve as a barrier for many potential ACO entities to participate within the program.** The proposed rule states that participating entities would be required to report on 65 total quality measures in five key domains: patient experience, care coordination, patient safety, preventive health, and at-risk population /frail elderly health. The expectation is too high, except possibly for large, already integrated groups with substantial data gathering infrastructure already in operation. The data reporting requirements are also substantially greater than those previously expected under both the Physician Group Practice (PGP) demonstration and the Hospital Inpatient Quality Reporting program. **The College suggests that the current proposal be changed to one using a combination approach that starts at a lower level of data reporting expectation that increases over time (a ramp-up approach) and also links the degree of quality data reporting requirements to the degree of risk and gain potential (i.e., the shared savings options) accepted by the entity.** Thus, those practice collaborations entering the program under the proposed up-side only option would initially have a lesser reporting requirement (e.g. a requirement to report on less measures) than those under the two-side or recently introduced Pioneer option.
- **The burden that the reporting mechanisms would have on physician practices, particularly on smaller practices.** The proposed rule reflects that only 11 of the quality measures are claims based and can be directly obtained by CMS. The remaining measure data sources, either survey data or data being reported through the Group Practice Reporting Option (GPRO) methodology, can be quite burdensome on the participating entities—regardless of the number of data elements required to be reported. It is essential that CMS set up systems to lessen this reporting burden—particularly by developing workable interfaces so that the necessary data can be easily abstracted from Electronic Health Records, and entities can be assisted to reasonably obtain the necessary survey data. The College further recommends that CMS include the use of data reporting through registries—this is particularly important to specialty practices participating within an ACO that already participate in substantial data reporting through registries developed by their specialty societies.

ACP also believes that there is a need to include risk-adjustment modifiers to the outcome measures, a need to monitor for inappropriate manipulation of the data through changes in diagnostic-coding practices (particularly for the ambulatory care sensitive measures) and a need to expand and clarify exclusion options when the following of evidence-based guidelines would be inappropriate for a given patient.

Public Reporting—CMS is proposing that ACOs publicly report certain information, including information relating to ACO participants, ACO joint venture arrangements and other organizational information, shared savings, and quality performance standard scores. CMS

further proposes that each ACO has the responsibility for making this information public in a standardized format that CMS will make available through subregulatory guidance. **The ACP agrees with CMS' proposal that ACOs themselves would be required to make this information publicly available, rather than reporting the information to CMS to make publicly available, and we urge CMS to maintain this proposal. We also urge that ACOs have the opportunity to review and verify the data CMS uses in developing performance standard scores before this data is required to be made public.**

Beneficiary Attribution Methodology—The proposed rule reflects that beneficiary assignment is based on the primary care physicians that provides the plurality (as reflected by charges) of patient care. Primary care is defined by a model that first specifies only a select group of providers (i.e. general practice, family practice, internal medicine, and geriatric medicine physicians), and then requires the designated primary care specialist to provide at least 60 percent of their Part B services from a select group of primary care services. This stepwise methodology is being used to insure that the attribution is made based on physicians who are actually providing primary care. **The College supports this methodology, but only with the inclusion of the following modifications, which were also recently made under the implementation of the Medicare Primary Care Incentive Program (PCIP):**

- **The 60 % requirement be based not on all Part B services, but only services billed through the Physician Fee Schedule; and**
- **Evaluation and Management Services within the hospital setting be removed from the denominator of the 60 % calculation.**

The first modification is to ensure that true primary care physicians who have in-office labs and perform a number of ancillary services aren't erroneously excluded, and the second modification helps ensure that primary care physicians that follow their patients within the hospital setting aren't erroneous excluded.

The proposed rule further defines a retrospective attribution methodology in which beneficiaries are assigned. The proposed rule outlines a rationale for this approach; that a certain percentage of beneficiaries attributed prospectively may change during the year, and ensuring that all beneficiaries in the physician patient panel, not just those attributed to the ACO, receive the same treatment. This rationale, though, underplays the negative aspects of this type of attribution and the benefits of prospective attribution. **As an alternative to retrospective attribution, the College recommends that a prospective attribution methodology be employed.** This will assist the ACO in actually knowing the beneficiaries for which they are accountable, and in obtaining the real time data necessary for successfully achieving the quality and cost outcomes that this shared savings model requires.

Under the current proposal, ACOs and their participating providers may need to wait for approximately 9 months after the end of the fiscal year to know who was actually included within their "defined accountable" population. This is not practical, and not consistent with good clinical and business practices. We acknowledge the concern that prospective attribution could in theory result in the ACO providing different standards of care to patients who are prospectively attributed to the ACO and those who are not. However, professional ethics and standards require

that physicians not provide a lower level of care to one group of patients compared to another; the profession's commitment to its own ethics therefore will mitigate against ACO's providing a lower level of care to patients not prospectively attributed to it.

Related to this attribution methodology issue is the current, proposed passive means of assigning beneficiaries to the ACO. CMS will automatically assign beneficiaries based upon the above described plurality method. While the proposed rule requires participating physicians to notify their patients that they are participating within the Medicare ACO program and engage in some information sharing regarding what that means, the beneficiary currently has no say regarding their involvement; except for choosing to change their primary care provider. Preferably, ACP would like beneficiaries to have a direct say on whether to be included within the defined ACO population. **We believe that a shared savings model will work best when patients themselves are positively engaged with working with their clinicians in the ACO to improve their own outcomes of care.** This would reinforce the need for CMS and participating physicians to highlight the benefits of participation and promote a more engaged beneficiary population. One practical way to accomplish this would be for CMS to send an informational letter to beneficiaries that have been prospectively assigned statistically to an ACO, prior to the onset of the program, to describe the program including possible benefits, reconfirm their continued freedom to choose providers, include an 800 number for further information, and provide opt-out options for both inclusion in the defined accountable population and data sharing (the data sharing opt-out option is already currently required in the rule) with a time definite response date. Beneficiaries can also be encouraged to discuss the program with their primary care physician.

If CMS decides not to implement the above recommended prospective attribution approach, the College recommends that CMS at least exclude beneficiaries that opt-out of data sharing from the defined accountable population. It is not reasonable to hold the ACO accountable, if they are denied access to important data that affects the effective and efficient provision of care.

Patient Education—the proposed rule highlights the importance of timely and effective communication with beneficiaries concerning the Shared Savings Program, their potential assignment to an ACO, and what that may mean for the beneficiaries' care. In order to facilitate this goal, the ACP recommends that **education efforts should be developed in cooperation with physicians and launched as soon as possible, and well in advance of the initiation of the ACO program on January 1, 2012.**

Beneficiary Attribution—Expanding the Definition of Primary Care Provider—The proposed rule specifically requested recommendations regarding expanding the definition of primary care in rural and similar underserved healthcare areas in which there are not a sufficient number of primary care physicians as defined to generate at least a minimum number of attributed beneficiaries. The current definition includes only the specialty designations of “family medicine, internal medicine, geriatric medicine, and general practice medicine” and the rule indicates that legislative language requires attribution through a physician. Based on the fact that all internal medicine subspecialty physicians are trained in providing primary care, the College offers the following suggestion. **In those difficult to attribute regions, the College**

recommends that the primary care definition be expanded to include those self-designated internal medicine subspecialty physicians that often fulfill the primary care needs of their patients, particularly when they are providing comprehensive and longitudinal care of the whole patient in addition to treating a serious principal condition within their subspecialty training. These subspecialty areas might include nephrology, oncology, rheumatology, endocrinology, pulmonology, and cardiology. As a second possible screen to ensure that the attribution is focused on the delivery of primary care, subspecialty physicians whose patients are attributed under this expanded definition can be asked to attest that they are providing the first contact, comprehensive care for that particular patient. Attribution would only take place if such an affirmative attestation is provided. This recommendation is a modification of the second-line primary care attribution methodology being used under the new Pioneer ACO option. **ACP would not support expanding the definition of “primary care provider” to other specialties who lack training in comprehensive primary care and/or who do not take care of the whole person because they limit their care to specific disease conditions or organ systems.**

ACO Governance Structure—ACP supports the concept that ACO participants must have at least 75 percent control of the ACO’s governing body. Further, that each ACO participant must choose an appropriate representative from within its organization to represent them on the governing body. **Given the primary care foundation of the proposed ACO model, the College recommends the addition of language within the regulations that ensures representation of primary care physicians in executive leadership positions of the organization.**

Distribution of Shared Savings—The proposed rule goes into great detail how CMS will share any earned savings with the ACO entity, but is silent regarding how the ACO should distribute the savings among its participants. In fact, CMS states that the issue of how ACOs distribute their shared savings earnings is beyond their regulatory authority. The primary care community is greatly concerned that large entities (e.g. hospital systems) will dominate ACO activities, and distribute any earned savings in a manner that doesn’t adequately reflect the significant contribution of the primary care physician toward earning those savings. The recent upswing of hospital physician employment and practice purchases (see “Entry Point” article in the April 2011 edition of *Health Affairs*) only serves to reinforce this fear. The College realizes that the required Governance structure and transparency rules of the ACO provide some protections to the participating primary care physicians from inequitable treatment; but these safeguards may not be sufficient. The College offers the following two recommendations to address this area of concern:

- **As part of the ACO application process, in addition to requiring the ACO to publicly report how it plans to distribute its earned shared savings to the participating providers, CMS also should require all applicants to explicitly address how they plan to maintain (including any planned financial incentives) a sufficient number of primary care physicians to adequately meet the needs of the defined accountable population during the term of the contract.**
- **Work with the Federal Trade Commission and the Department of Justice to develop safe harbors through which primary care physicians participating within an ACO,**

under defined situations, could organize and negotiate their contractual arrangements in a collective manner.

Limitation of Primary Care Physicians to One ACO—The proposed rule limits defined primary care physicians to participate in only one ACO. The College believes that this exclusivity requirement inappropriately and artificially limits the aligning quality and efficiency benefits of the ACO program. We have already heard from primary care physicians in different parts of the country who anticipate two or more ACOs (typically through competing hospital systems) being developed. In many such instances, their patients are evenly split between the two systems (and the services they provide) typically based upon their geographic proximity to their residence. By limiting the primary care physician to just one system, that physician would have diminished incentive to promote the goals of the ACO model to those of his patients being treated through services provided by the non-selected ACO. They will also be unable to benefit from the successful quality and efficiency efforts of the non-selected ACO. **Thus, we recommend that the primary care physician used for attribution not be limited to one ACO.** Furthermore, to avoid the problem of attributing patients to more than one ACO, **we recommend that in those areas in which there are competing ACO entities in which the primary care physician has some affiliation, the beneficiary can be given the option to select their attributed ACO, the physician can choose which of the competing ACOs to assign the specific patient to, or CMS can make the determination based upon which of the entities account for the highest amount of charges attributable to their provider participants.**

Benchmarking Methodology—The proposed rule reflects that expenditure benchmarks will be based on the most recently available three-year expenditure histories for those Medicare beneficiaries that would have been assigned to the ACO if it existed. CMS further proposes to use the CMS-Hierarchical Conditions Categories (HCC) methodology to risk adjust these expenditure totals—but this first year adjustment will be used throughout the three year contract. ACP believes that this planned benchmarking methodology is inappropriate and leads to unnecessary inequities. The College makes the following recommendations:

- The use of only these “local” data to establish benchmarks unfairly punishes those areas of the country and groups of practitioners that have already made significant efforts towards providing efficient care. A more appropriate approach would be to establish the benchmark based upon either some combination of local and national expenditure data or national expenditure data alone.
- The lack of a dynamic process to assess the risk status of the defined population and modify the expenditures benchmark as appropriate for each year of the contract denies the cited data of an approximately 25 % beneficiary turnover in defined population each year. Any changes in the severity of health status of the defined population from year to year should be reflected in the benchmarks. This process would be made much easier should CMS choose to follow ACP’s previous recommendation for a prospective model of attribution.

Meaningful Use Requirement—The proposed rule states that by the second year of the contract, at least 50 percent of participating primary care participants within the ACO be a “meaningful user.” **The College supports the importance of Electronic Health Record (EHR) adoption, but believes that this 50 % requirement may be too high a goal—particularly for small and**

intermediate size practice collaborations considering participating within the ACO program. This concern is further magnified by the fact that the more difficult Stage 2 criteria for Meaningful Use will be in effect in 2013. The College suggests, similar to the overall multi-entry perspective discussed earlier in this comment letter, that the meaningful use requirement be reduced and made variable based upon the degree of risk and gain potential accepted by the entity. Requirements at each option level can be ramped-up over time.

Recognition of ACOs that Contain Primary Care Practices that Achieve PCMH-Recognition from an Approved National Entity—There is a strong complementary relationship between the PCMH care delivery model and the goals of the ACO program. In fact, ACP believes that well-functioning, patient-centered primary care practices should be viewed as being foundational to ACOs. The requirements of a PCMH recognized practice regarding enhanced access, care coordination and integration, and improved quality and safety are the type of physician practice processes that allow an ACO to be successful. **As a result, the College recommends that there be some incentive within the proposed ACO program to encourage the involvement of PCMH-recognized practices within the ACO.** For example, ACOs that have a high percentage of PCMH-recognized participants could be exempt from certain regulatory requirements or be allowed to earn a bonus share of any obtained savings.

Encouraging the Involvement of Collaborations of Small and Medium Size Physician Practices to Enter into the ACO program—Various recommendations have been made through this letter toward the goal of allowing a wider diversity of practice collaborations to enter the pathway toward meeting the goals of the Accountable Care program. Approximately 50 percent of ACP members are in physician practices of 5 or less; with approximately 20 percent in solo practice. Many of these physicians want to engage in processes that improve quality, are more efficient and save limited healthcare resources, provide better coordination of care within the medical neighborhood, and are patient-centered. Many of these practices would be interested in developing collaborations with similar practices in their geographic location toward these aims. **These efforts will require significant assistance to achieve these goals, some of which could be provided either through changes in the current proposed rule or through new initiatives offered through the CMMI focused specifically to encourage such collaborations. Minimal components in such a program would be:**

- **The availability of an up-side only shared savings option;**
- **The availability of access to developmental capital in such forms as no-cost loans, competitive developmental grants, and advanced up-front payments of expected savings;**
- **Technical assistance in the establishing of these collaborative potential ACO entities and in achieving the necessary administrative, operational, and service delivery requirements to successfully function under this delivery and payment model.**

A significant amount of care is provided to Medicare beneficiaries by these small and medium size practices throughout the country, and the College encourages CMS to seriously consider how to help these practices begin on the pathway toward being able to be truly accountable for the care provided. The recently introduced Advanced Payment ACO option and the ACO Accelerated Development Learning Sessions are good first-steps in this direction.

The Shared Savings/ACO program defined under this proposed rule represents an earnest attempt to improve the quality and efficiency of healthcare delivered to our Medicare beneficiaries. The comments and recommendations made by the College through this letter attempt to both improve the program's implementation, and provide access to an increased number and diversity of practice collaborations that could choose to enter into the program. **Given that this is a completely new Medicare delivery and payment model, ACP urges CMS to issue an interim final rule, rather than a final rule, so that CMS maintains the flexibility to modify and improve the ACO regulations.** Please contact Neil Kirschner at nkirschner@acponline.org or 202-261-4535 if you have any questions regarding the recommendations provided.

Respectfully,

A handwritten signature in black ink, appearing to read "Don Hatton MD FACP". The signature is fluid and cursive, with the letters "MD" and "FACP" written in a slightly larger, more distinct font than the name.

Don Hatton, MD, FACP
Chair, Medical Practice and Quality Committee