I think it is very important that the **Advance Payment Initiative** should have a requirement that those who enter into Advance Payment must have enough Case Managers and Social workers to assist Medicare patients with proper discharge planning and accurate follow up with them to prevent unnecessary hospital admissions or ER visits. I think it is crucial to this initiative to have the proper staffing that can work with patients from day one they enter the care system and to follow up with them after their initial visits with the CPC and/or after their discharge from the hospital.

Layla Abdul-Ghani, LMSW, ACSW, CCM, CCP
Social Worker
Case Management Dept.
BCBSM

AMERICAN ACADEMY OF FAMILY PHYSICIANS

STRONG MEDICINE FOR AMERICA

May 20, 2011

Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
P.O. Box 8013
Baltimore, MD 21244–8013

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

Dear Dr. Berwick:

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 100,300 family physicians and medical students nationwide, I am writing in response to ~~"M~~Medicare Shared Savings Program: Accountable Care Organizations" (CMS–1345–P) proposed rule as published in the April 7, 2011, *Federal Register*.

Sec. 3022 of the *Affordable Care Act* requires the Centers for Medicare & Medicaid Services (CMS) to establish a voluntary, three-year program ~~*by Jan. 1, 2012 that promotes accountability for a patient population, coordinates items and services under Medicare Parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery*~~." Participating entities, referred to as Medicare Accountable Care Organizations (ACOs), that meet quality and performance standards are eligible to receive payments for shared savings.

The AAFP recognizes this proposed regulation as the first major health delivery reform initiative following the passage of the *Affordable Care Act*. As a longstanding supporter of efforts that improve the quality and efficiency of care and efforts that demonstrate an increased value of healthcare expenditures, we believe properly structured ACOs have the potential to help make the delivery system more accountable and more focused on value instead of volume.

However, the AAFP is concerned that the Medicare ACO program as currently proposed will fail to offer the potential benefits of better care for individuals, better health for populations, lower per capita costs for Medicare beneficiaries and improved coordination among physicians. The AAFP remains committed to working with CMS and the Congress to refine the Medicare Shared Savings ACO program to ensure its success.

To improve the final Medicare ACO regulation, the AAFP offers the following detailed recommendations related to this rule. Key recommendations include urging that CMS:

- Identify alternative policies so that primary care physicians are able to participate in multiple Medicare ACOs;

- Not confine its payment method to the current, traditional Medicare fee-for-service payments to ACO participants but instead employ a variety of payment approaches, such as blended fee-for-service payments, prospective payments, episode/case rate payments, and partial capitation payments;
- Drastically reconsider its proposed Medicare ACO policies and instead offer greater flexibility so that small- to medium-sized primary care practices will be more eligible to participate;
- Consider proposing additional tracks that are tailored for smaller medical practices less familiar with assuming financial risk;
- Specify that the Medicare ACO governance structure must utilize primary care physicians in the top leadership positions to ensure that Medicare ACOs are primary care driven; and
- Outline quality reporting requirements for the full three-year program, significantly reduce the number of required quality measures, and only require reporting on quality measures that improve population health outcomes and efficiency.

Medicare ACO Eligibility

An ACO typically refers to a group of physicians, hospitals and other suppliers of services that will work together to provide coordinated care to a specified patient population. For purposes of the Medicare Shared Savings Program, CMS defines five types of entities permitted to form Medicare ACOs:

- ACO professionals (physicians, physician assistants, nurse practitioners and clinical nurse specialists) in group practice arrangements;
- Networks of individual practices of ACO professionals;
- Partnerships or joint venture arrangements between hospitals and ACO professionals;
- Hospitals employing ACO professionals; and
- Critical Access Hospitals that bill for the facility and the professional services to their fiscal intermediary or their Medicare Part A/B Medicare Administrative Contractor.

Although only these five entities can form a Medicare ACO, other Medicare providers and suppliers may participate.

In the proposed rule, CMS anticipates aggregate start-up investment and first-year operating expenditures for Medicare ACOs will be between $131 million and $263 million. The AAFP is quite concerned that, as currently proposed, only large and established integrated health systems that already possess the capital and infrastructure would be able to qualify as a Medicare ACO. Failing to attract small- to medium-sized practices, especially in rural settings but also in urban areas, will squander this tremendous opportunity to improve the healthcare delivery system and will deny the potential benefits of the ACO model to patients throughout the country, most of whom receive care from small and medium size physician practices.

The AAFP urges CMS to drastically reconsider its proposed Medicare ACO policies and instead offer greater flexibility so that small- to medium-sized primary care practices will be more eligible to participate. This would involve eliminating all but the essential requirements included in the statute (e.g., demonstrated ability to care for at least 5,000 beneficiaries, ability to measure and report on quality of care provided) and making the ~~o~~ne-sided model" truly one-sided. CMS's concern with the minutiae of ACO governance and management structure and marketing seems misplaced. If CMS focuses only on the essentials and allows ACOs to take shape in ways that make the most sense in their respective markets, then small- to medium-sized practices will have more opportunity to participate, and Medicare patients will reap the rewards of their doing so.

The AAFP, therefore, encourages CMS and the Center for Medicare and Medicaid Innovation to offer significantly different Medicare ACO participation options in the final Medicare ACO regulation and in future efforts to experiment with innovative payment methodologies.

Medicare ACO Structure

As proposed, a Medicare ACO will be a legal entity that is recognized and authorized under applicable state law and is identified by a Taxpayer Identification Number (TIN). Providers and suppliers participating in a Medicare ACO not only will continue to receive traditional fee-for-service payments under Medicare Parts A and B, but also will be eligible to receive a portion of the shared savings if successfully satisfying quality performance standards and reducing healthcare costs.

The AAFP does not believe that the Medicare ACO program can succeed if CMS confines its payment method to the current, traditional Medicare fee-for-service payments to ACO participants. Per the AAFP principles on ACOs, we urge CMS to revise the proposed policies and instead employ a variety of payment approaches, such as blended fee-for-service payments, prospective payments, episode/case rate payments, and partial capitation payments. Sec. 3022 of the *Affordable Care Act* discusses a partial capitation model, yet CMS unaccountably did not include this model in the proposed regulation. The AAFP believes continuing traditional fee-for-service payment on a day to day basis is an approach that lacks sufficient financial incentives to motivate ACO participants to improve the coordination of patient care. The incentives derived from potential shared savings, which the Medicare ACO may or may not receive many months after clinical care is provided, will be small in relation to the fee-for-service payments derived from visits or procedures, making it difficult for ACO management to effect the needed changes.

One of the main challenges for any ACO is to modify physicians‘ behaviors, and the AAFP believes the best mechanism to achieve this is through immediate reinforcement in the form of payment for services provided directly in the office and indirectly through contacts like e-mail and telephone as well as a per-patient/per-month care management fee. Unless or until CMS is able to pay ACOs (and, in turn, facilitate ACOs paying their participants) in a manner more consistent with the desired outcomes (i.e., through a blend of fee-for-service, partial capitation, etc.), we do not believe the Medicare ACO program can succeed. We therefore encourage CMS and the Center for Medicare and Medicaid Innovation to further consider and experiment with payment models outside the limitations of Sec. 3022.

The AAFP is pleased that CMS proposes a requirement that at least 75 percent of a Medicare ACO‘s leadership and governance structure must consist of clinicians, administrative staff, and patients. Since Congress intended the Medicare ACO program to be based on a foundation of primary medical care, we urge CMS, in the final rule, to specify that the Medicare ACO governance structure must utilize primary care physicians in the top leadership positions to ensure that Medicare ACOs are primary care driven. Significant and equitable representation from primary care and specialty physicians in a Medicare ACO‘s administrative structure, policy development, and decision-making processes will help to ensure the program‘s success.

Also commendable is the requirement that all Medicare ACOs employ a board-certified physician, licensed in the state in which the ACO operates, who is physically present in an established ACO location and who serves as a senior-level medical director responsible for clinical management and oversight. Similarly, we support the provision requiring all Medicare ACOs to employ a physician to direct the quality assurance and process-improvement committee. We concur with CMS that physicians, especially primary care physicians, serving in these leadership positions will promote continued quality improvement efforts.

Shared Savings Methodology

To the extent participating providers meet certain quality standards and savings benchmarks, such providers can receive payment for shared Medicare savings limited by benchmarks, thresholds and caps. As proposed, participating Medicare ACOs have the option to select one of two payment models, depending on the experience level of the ACO and willingness to assume a share of the risk.

- Track 1 (one-sided model): Shared savings are reconciled annually for the first two years of the three-year term using a pure shared savings approach whereby the ACO is not responsible for any portion of any losses. In the third year, the ACO is required to share in any losses generated, as well as any savings. For Track 1, the minimum savings rate ranges from 2 percent for Medicare ACOs with over 60,000 beneficiaries to 3.9 percent for Medicare ACOs with only 5,000 beneficiaries.
- Track 2 (two-sided model): A risk-based model is used for the entire three-year term. The ACO is eligible for higher sharing rates and other benefits in return for the increased risk of sharing in any losses for all three years of the agreement. Track 2 Medicare ACOs may receive to up to 60 percent of the gross savings beyond the minimum savings rate and up to the maximum sharing cap of 10 percent of the expenditure benchmark.

The AAFP appreciates CMS offering risk-based options to potential Medicare ACOs, but we urge CMS to consider proposing additional options tailored for smaller medical practices. To encourage greater participation, the AAFP recommends easing the 2 percent to 3.9 percent minimum savings rate, as these rates are too high to entice small- to medium- sized primary care practices, less familiar with assuming financial risk, to consider becoming part of a Medicare ACO. CMS should also eliminate the cap on shared savings. Doing so may increase interest and may improve participation in the program. The statute anticipates that professionals in group practice arrangements should be permitted to form Medicare ACOs. Requiring all Medicare ACOs to assume down-side risk in at least the third year will also discourage small- and medium-sized practices from forming a Medicare ACO. Mandatory risk-sharing for all Medicare ACO participants will be problematic, particularly as the Medicare ACOs will have no ability to identify their assigned beneficiaries or influence their behavior.

Despite the proposed rule‘s discussion of the shared savings methodology, potential Medicare ACOs are still unable to determine possible shared savings for several reasons. To measure likely Medicare expenditures in the absence of the ACO, CMS must establish each ACO‘s expenditure benchmark, calculated based on the most recent available three years of per-beneficiary expenditures for Medicare Parts A and B services for those beneficiaries assigned to the ACO. Without access to recent Medicare claims data or knowledge of how beneficiaries will be assigned to ACOs, potential Medicare ACOs are unable to estimate their expenditure benchmarks. This inability to determine potential Medicare shared savings will further discourage initial participation. The AAFP thus encourages CMS to provide estimated expenditure benchmarks to entities prior to the formal ACO application process so that the prospective ACO participants can make a more informed business decision.

Quality Reporting Requirements

For the first year, CMS proposes that the Medicare ACOs report 65 quality measures on patient and caregiver experiences, care coordination, patient safety, preventive health, and at-risk populations. Quality measure reporting requirements for the second and third year will be created during future rule-making. Under the current proposal, Medicare ACOs that demonstrate that they are providing high quality care are eligible for a portion of the shared savings.

The AAFP questions why CMS proposed quality reporting requirements for the first year only, while requiring potential Medicare ACOs to commit to participating for three years. Instead, the AAFP urges CMS to outline quality reporting requirements for the full three-year program. CMS must do this so that interested entities are fully aware of all Medicare ACO program requirements.

Furthermore, the AAFP believes the number of initial quality measures is, at least for the first year, onerous and operationally unrealistic. We note that the Physician Quality Reporting System only requires three measures, and the response to that program has not been overwhelming. We therefore urge CMS to specify clearer parameters pertaining to reporting on quality measures. Quality measure reporting must be handled

with great care and must yield accurate, timely, and actionable data. The value of quality measures is to provide timely and actionable feedback to the Medicare ACO and its participating physicians so that they can then modify practices, behaviors and systems. Medicare ACOs should be allowed to choose which NQF endorsed quality measures apply to that ACO's covered population. CMS should only require Medicare ACOs to report on quality measures that improve population health outcomes and efficiency.

The *Affordable Care Act* does not require a hospital to be a part of a Medicare ACO. It is therefore puzzling that CMS proposes all Medicare ACOs must report a measure that incorporates 9 hospital acquired condition measures. The measure set should be limited to a more feasible list (e.g., 10 measures) in the first year, focusing on addressing high cost/high volume disease conditions, with the remaining measures phased-in over the three-year performance period. Another option is to have reporting requirements for the first year, without targets or penalties, and phase those in after year one or two. Furthermore, the AAFP has concerns over the proposed quality measure scoring process, the overall performance score, the performance benchmarks, and the minimum attainment level for each quality measure. This is an overly complicated process that should be significantly streamlined. These types of complexities further exclude smaller and less integrated primary care practices.

CMS proposes that Medicare ACOs publicly report information on providers and suppliers participating in the ACO, parties sharing in the ACO governance, quality performance standard scores, and general information on how a Medicare ACO shares savings with its members. AAFP supports these efforts as a way to ensure transparency. Furthermore, we commend CMS for aligning the Medicare and Medicaid Electronic Health Record incentive program with the Medicare ACO quality reporting requirements and urge continued alignment in future rulemaking.

Role of Primary Care

By statutory requirement, ACOs must ~~"~~*include primary care ACO professionals that are sufficient for the number of Medicare fee-for-service beneficiaries assigned to the ACO*" and ~~"~~*at a minimum, the ACO shall have at least 5,000 such beneficiaries assigned to it*." For purposes of the Medicare Shared Savings Program, CMS defines ~~"~~primary care professionals" as physicians who have a primary specialty designation as ~~"~~internal medicine, general practice, family practice, or geriatric medicine" and who are providing the appropriate primary care services to beneficiaries. For purposes of Medicare ACOs, CMS proposes to define "primary care services" as those identified by HCPCS codes 99201 through 99215, 99304 through 99340, 99341 through 99350, the Welcome to Medicare visit (G0402), and the Annual Wellness Visits (G0438 and G0439). We urge CMS to specify ~~"~~general internal medicine" in the final Medicare ACO regulation to ensure that Medicare ACOs are truly based on primary care physicians. We propose that the definition of primary care professionals for purposes of the Medicare ACO program only include "general internal medicine, general practice, family medicine, or geriatric medicine" in any of their specialty designation fields, primary, secondary or otherwise.

We further recommend that rather than list "primary care services," that CMS go further to state that the primary care professionals be limited to those eligible for Primary Care Incentive Payments as a matter of consistency and specificity across CMS policy. The AAFP recognizes that some sub-specialists occasionally provide some primary care services. However, they are not providing continuing and comprehensive primary healthcare to their patients. The AAFP would strongly oppose any further expansions of the definition of ~~"~~primary care professional" for purposes of the Medicare ACO program.

With respect to defining ‗primary care services'' for the purposes of assigning beneficiaries under the Medicare ACO program, CMS proposes and seeks comments on three options:

1. Assignment of beneficiaries based upon a predefined set of ‗primary care services;''

2. Assignment of beneficiaries based upon both a predefined set of ‗primary care services'' and a predefined group of ‗primary care providers;'' and
3. Assignment of beneficiaries in a stepwise fashion.

The first option assigns beneficiaries by defining ‗primary care services'' on the basis of the select set of E&M services, specifically those defined as ‗primary care services'' for purposes of the Primary Care Incentive Program and including G-codes associated with the Annual Wellness Visit and Welcome to Medicare benefit regardless of provider specialty. Though this option increases the number of potential beneficiaries assigned to the ACO in areas with primary care shortages and is administratively straightforward for CMS, the AAFP strongly opposes this proposed method. The AAFP believes assigning beneficiaries to Medicare ACOs based only on primary care services without distinction of physician specialty increases the likelihood of assigning beneficiaries to a specialist instead of a primary care physician. We believe this is inconsistent with the statutory requirement that Medicare ACOs rest on a foundation of primary medical care. We concur with the CMS commentary in the proposed rule that this option would diminish the appropriate level of emphasis on a primary care core in the Medicare ACO program by failing to place any priority on the services of designated primary care physicians in the assignment process.

Under the third option, beneficiary assignment would proceed by first identifying primary care physicians (internal medicine, family medicine, general practice, geriatric medicine) who are providing primary care services, and then identifying specialists who are providing these same services for patients who are not seeing any primary care professional. The AAFP opposes this option since specialists do not provide the entire range of primary care services. By failing to place any priority on primary care physicians that deliver comprehensive and continuous care for the full range of primary care services in the assignment process, we consider this option to be inconsistent with the *Affordable Care Act's* emphasis on a primary care core in the Medicare ACO program.

The second option proposed by CMS is to assign beneficiaries to physicians designated as primary care providers (internal medicine, general practice, family medicine, and geriatric medicine) who are providing the appropriate primary care services to beneficiaries. The AAFP believes this option is more closely aligned with the definition of primary care services as intended under the *Affordable Care Act,* and this approach is consistent with implementation of the Primary Care Incentive Program. As in the case of the first option, this option would be relatively straightforward administratively.

The AAFP believes the second option is the best of the three proposals; however, it limits primary care physicians to participate in only one Medicare ACO. Prior to publication of this proposed regulation, CMS conducted multiple ACO listening sessions, special conference calls, and workshops, and the agency issued a formal request for information. Throughout these opportunities to provide feedback, the AAFP and other national medical societies consistently urged CMS to allow primary care physicians as well as specialty physicians and other healthcare professionals to have the option to participate in multiple Medicare ACOs. For the Medicare ACO program to succeed, it is absolutely essential for CMS to identify alternative policies so that primary care physicians are able to participate in multiple Medicare ACOs.

Limiting primary care physicians that wish to participate in the Medicare Shared Savings Program to only one Medicare ACO could compel them to simply not participate at all. Family physicians and other primary care physicians provide healthcare services to a variety of Medicare patients that often receive further care in multiple tertiary centers and various hospitals. By locking primary care physician participation into only one Medicare ACO, CMS essentially is limiting ACO participation to only a portion of the primary care practice's Medicare patient population. This proposed policy reinforces our belief that the regulation offers very little incentive for even the most sophisticated primary care practice to pursue Medicare ACO participation.

The AAFP recognizes CMS must assign Medicare fee-for-service beneficiaries to a specific ACO based on their utilization of primary care services. As proposed, the primary care physician with the plurality of visits determines to which Medicare ACO the patient is assigned, and if the primary care physician participated in two Medicare ACOs, confusion over to which one CMS should assign a patient may arise. However, this problem could be avoided by creating incentives (e.g., no deductibles and reduced co-insurance for primary care physician services) for patients to prospectively identify a primary care physician in an ACO. The patients need to be accountable as well as the participating physicians and providers. Identification of a primary care physician does not have to limit patient choice in any way. It simply provides an alternative method for identifying the population of patients for which the ACO is responsible while getting more engaged patients to think about having a usual source of care.

Alternatively, CMS should prospectively allow patients to choose their own Medicare ACO. This would relieve CMS from the proposed and flawed beneficiary attribution method that currently limits primary care physicians to participate in only one Medicare ACO.

The AAFP reminds CMS that the *Affordable Care Act* requires Medicare ACOs to demonstrate patient-centeredness systems. The AAFP is a longstanding advocate for concepts that provide everyone with a patient-centered medical home, an enhanced model of practice offering quality, comprehensive primary care. Family physicians—the majority of whom have adopted health information technologies into their practices—are committed to delivering team-based care. For these reasons, family physician practices are best situated to provide coordinated care to Medicare beneficiaries, a fundamental objective of the Medicare ACO program. Participation by small- and medium-sized primary care practices will be essential for the success of Medicare ACOs, and CMS ought to reconsider the beneficiary attribution method so that primary care physicians may participate in multiple Medicare ACOs.

The AAFP concurs with the CMS proposal to offer Medicare ACOs flexibility in adding or removing providers‘ National Provider Identifier numbers. This is especially important for small or rural Medicare ACOs to flourish over the course of the three-year agreement.

Involvement of Medicare Beneficiaries in an ACO

The AAFP supports the flexibility offered to Medicare patients receiving care in a Medicare ACO. For instance, the agency specifies that participation of Medicare beneficiaries is completely voluntary and there is no automatic enrollment or assignment of beneficiaries to the Medicare ACO. The proposed regulation also allows Medicare beneficiaries to receive care outside of the Medicare ACO at no penalty to the patient.

The AAFP concurs with the proposed requirements that Medicare ACOs notify patients at the point of care that their provider or supplier is participating as a Medicare ACO. We also agree with the proposed condition that Medicare ACOs must obtain a patient‘s permission to request that patient‘s Medicare claims data. According to our principles on ACOs, we believe patients receiving care in a Medicare ACO should be encouraged to prospectively select a primary care physician. We urge CMS to consider this as a resolution to the problem that, as currently proposed, primary care physicians could only participate in one Medicare ACO.

Participation in Rural Areas

CMS requests comments on payment mechanisms for rural primary care practices under Medicare ACO payment methodologies. The participation of small rural practices in Medicare ACOs is essential for Medicare beneficiaries, especially given the statutory requirement that Medicare ACOs have 5,000 beneficiaries.

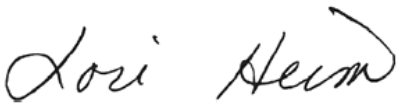
Small- and medium-sized primary care practices in rural areas will encounter additional challenges with the Medicare ACO program. If they attempt to participate, they will be compelled to align with larger entities that possess the robust financial resources needed to fund health information technology infrastructure and sufficient reserves to fund any possible losses. For purposes of the Medicare ACO, rural primary care practices likely will not band together in an independent practice association (IPA) arrangement since IPAs, especially new IPAs, typically lack the needed financial reserves. A rural primary care practice could participate with the local hospital as a Medicare ACO. This is problematic as these small hospitals are not positioned to be successful ACOs.

To address the considerable challenges individual physicians in rural areas face, the AAFP urges CMS to consider further incentives, such as an enhanced fee-for-service payment and other payment methods (e.g., partial capitation), for joining a Medicare ACO. This rural primary care provider incentive could help to fund the infrastructure requirements of a Medicare ACO, buffer risk, and stimulate further participation. CMS should consider offering start-up grants or low-cost loans to entities wishing to create an ACO in a rural area. CMS must offer different Medicare ACO participation requirements for rural areas.

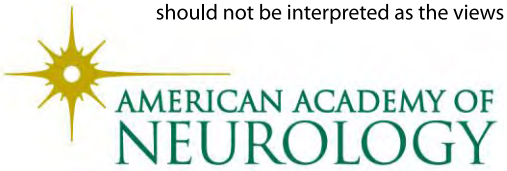
Conclusion

The AAFP recognizes that this regulation is only a proposal, and we hope that CMS ultimately finalizes the Medicare ACO requirements so that appropriately structured Medicare ACOs successfully make the healthcare delivery system more accountable. We remain committed to working with CMS on efforts that focus on better healthcare, better health, and lower costs. We appreciate the opportunity to provide these comments and make ourselves available for any questions or clarifications you might need. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org.

Sincerely,



Lori J. Heim, MD, FAAFP
Board Chair



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June 17, 2011

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Centers for Medicare and Medicaid Services
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Richard Gilfillan, MD
Director
Center for Medicare and Medicaid Innovation
7500 Security Blvd.
Baltimore, MD 21244

Dear Drs. Berwick and Gilfillan:

The American Academy of Neurology (AAN, Academy) is the premier national medical specialty society for neurology, representing 24,000 neurologists and neuroscience professionals, and is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a doctor with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system such as Alzheimer's disease, stroke, migraine, multiple sclerosis, brain injury, Parkinson's disease, and epilepsy.

The Academy is pleased to see that the Centers for Medicare and Medicaid Innovation (CMMI) is considering an Advanced Payment initiative to increase the participation rate in the Centers for Medicare and Medicaid Services' (CMS) shared savings program because the Academy believes start-up costs will be a significant barrier to participation in the program. In our June 6 comment to CMS on its shared savings program, we opined that the availability of shared savings needed to be increased in order to maximize participation, particularly if small accountable care organizations (ACO) would be willing to face the estimated $1.7 million in average start-up costs. Furthermore, the Academy also commented to the Health and Human Services Office of the Inspector General that the anti-kickback and physician referral law waivers should be extended to cover the formation of an ACO. The extension of the waiver would make it significantly easier for small organizations – which do not have ready access to capital – to raise the funds to cover the start-up costs of forming an ACO. Similarly, the Advanced Payment initiative would make it easier for small organizations to fund the ACO start-up costs.

While the AAN feels the Advance Payment initiative would increase participation in the shared savings program, the Academy is concerned with how CMS would collect advance payments in the event an ACO does not achieve shared savings. This element of the initiative is crucial to its success. The AAN wants to make sure that CMS does not use draconian methods to collect the advance payments made to ACOs such as pursuing the personal assets of the physicians that formed and participated in the ACO.

The shared savings proposed rule requires ACOs to be an entity recognized by a state, but it does not mandate any particular type of entity. The proposed rule specifically states ACOs could be partnerships, corporations, limited liability corporations, foundations, or any other state recognized entity. There are advantages and disadvantages to each different type of legal structure, with no one type fitting every organization that wishes to participate in the shared savings program. While each state

has different laws, there are typically different levels of liability that can be incurred by the owners of the organization. For example, corporations are often considered separate entities from their owners, while partnerships frequently are not. The practical effect of this distinction is that physicians participating in an ACO formed as a partnership are more likely to use their personal assets to pay ACO debts than physicians participating in an ACO formed as a corporation. A typical hallmark of a partnership is that it does not protect the personal assets of those in the partnership. This type of legal structure could leave the personal assets of the participating physicians unprotected in the event an ACO receives an advanced payment but does not manage to achieve shared savings. Presumably, the ACO must still pay the advanced payment back.

The Academy is concerned that unless CMS gives assurances that it will not pursue the personal assets of physicians in an ACO which receives an advanced payment, only ACOs organized as corporations may be willing to receive an advanced payment and the shared savings program may not be attractive to a diverse set of ACOs. Consequently, the AAN feels that CMS should detail how it will pursue return of any advanced payment to ACOs and it should treat all ACOs the same regardless of how they are organized.

The AAN looks forward to reviewing any further details of the Advanced Payment initiative should CMMI or CMS chose to release further details for comment. Thank you for your attention to the comments listed above. Should you have questions or require further information, please contact Mark Pascu, AAN Manager Regulatory Affairs at mpascu@aan.com or at 202-525-2018.

Sincerely,

Bruce Sigsbee, MD, FAAN
President
American Academy of Neurology

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June 17, 2011

Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Baltimore MD 21244-8013

Dear Dr. Berwick:

The American College of Cardiology (ACC) is pleased to offer brief comments on the Advanced Payment Initiative for Accountable Care Organizations (ACOs) as requested by the Centers of Medicare and Medicaid Services (CMS).

The American College of Cardiology is transforming cardiovascular care and improving heart health through continuous quality improvement, patient-centered care, payment innovation and professionalism. The College is a 40,000-member nonprofit medical society comprised of physicians, nurses, nurse practitioners, physician assistants, pharmacists and practice managers, and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The College is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The ACC provides professional education and operates national registries for the measurement and improvement of quality care. More information about the association is available online at http://www.cardiosource.org/ACC.

CMS requested opinions on whether prepaying a portion of shared savings could increase participation in the Medicare Shared Savings Program. As we expressed in our letter commenting on the proposed ACO regulation, we believe there are substantial upfront costs for providers that wish to form an ACO. We believe that a lack of available capital may reduce the number of providers who pursue this option, particularly those who are not already part of an integrated healthcare system. For this reason, we support a CMS proposal to offer some portion of assumed shared savings as an upfront cost to ACOs.

It appears from the brief proposal that CMS would distribute these funds as a monthly check during the ACO participation to help to cover these costs. We believe that this may not be effective as some of the costs of care coordination and health information technology require substantial payment to acquire. We believe it would be more appropriate to offer ACOs the opportunity to receive a large portion of the funds immediately in order to cover these upfront costs. In addition, we recommend that these funds be offered as an upfront payment for expected capital costs rather than as a loan. If shared savings are achieved as a result of this investment, then we support that these advanced payments be withheld from that shared savings. Based on the response to the ACO proposed rule, it is clear that providers will need more of an incentive to take on this increased responsibility and offering this necessary capital at this rate will likely increase participation.

We are aware that making money available in this fashion could attract those who are not serious about the goals of reducing costs and improving quality. We believe that the documentation associated with forming an ACO required will act as significant protection to ensure that ACOs that are offered this opportunity are serious about their responsibility and role in the system.

The ACC believes that this kind of funding will be most needed by small ACOs that are physician-run that may not include large organizations such as hospitals. We believe that CMS may want to limit their use of these upfront payments to small ACOs and to those who would not have easy access to capital for these purposes. This would best serve the agency's intention of fostering ACOs that might not be formed absent this funding mechanism.

We look forward to further work with CMS to create meaningful incentives to move our payment system towards one more focused on quality outcomes. If you have any questions, please contact Brian Whitman, Associate Director of Regulatory Affairs at bwhitman@acc.org or (202) 375-6396.

Sincerely,

David R Holmes

David R. Holmes, Jr., MD, FACC
President

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Submitted electronically to: *advpayACO@cms.hhs.gov*

June 17, 2011

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Advance Payment Initiative for Accountable Care Organizations entering the Medicare Shared Savings Program

To Whom It May Concern:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) commends the Centers for Medicare & Medicaid Services (CMS) for considering an Advance Payment Initiative for potential Accountable Care Organizations (ACOs) that are considering participating in the Medicare Shared Savings Program (MSSP). We thank CMS for the opportunity to provide suggestions on how the agency can partner with providers to make the investment necessary to become an ACO.

We support the CMS Innovation Center's concept of the Advance Payment Initiative to test whether and how pre-payment of a portion of future shared savings through monthly installments could increase participation in the MSSP. We encourage CMS to be flexible in:

- estimating the appropriate monthly amount that should be disbursed;
- determining how the reconciliation process between the pre-payments and the calculation of shared savings would be implemented; and
- establishing the process by which nascent ACOs would pay back the pre-payments if adequate shared savings were not achieved.

We fully understand and support the goal of reducing annual per capita expenditures; however, several experienced organizations that participated in previous CMS demonstration projects, including the Physician Group Practice (PGP) demonstration, reduced expenditures but did not

receive a shared savings bonus. In the PGP demonstration, for example, the parameters CMS used to calculate the shared savings bonus were too ambitious to allow many of the participants to share in savings. The AHA submitted detailed recommendations in its June 1 response to CMS' proposed regulation for the MSSP to suggest ways to improve the balance between reducing expenditures and sharing in savings.

Formation of an ACO will require significant upfront investment, and we urge the CMS Innovation Center to combine the Advance Payment Initiative with a grant program to offset the extensive investment needed to form an ACO, particularly in the case of small and/or rural hospitals and other organizations. We encourage CMS to consider investments beyond pre-payment of future bonuses because ACOs will need to make investments that go well beyond what they will potentially earn in shared savings bonuses. At the direction of the AHA, McManis Consulting recently completed four case studies to assess the capabilities required to be successful as an ACO and the associated costs. These four case study organizations vary in size and type, including a large health system, a physician-only group practice, a single hospital community system and an independent practice association affiliated with a hospital system. Additional information on each of the case studies is available at www.aha.org/ACOcasestudies. These four case study organizations reside in four distinct geographic areas and represent different models for ACO development. McManis Consulting identified 23 dimensions and costs related to establishing an "ACO-like" organization (see Attachment).

These case studies provide the supporting research for a report documenting the costs of becoming an ACO, which we have made publicly available.[1] **Estimates by McManis Consulting have determined the combined start-up and first-year ongoing costs are much higher than CMS estimated. Specifically, for a small ACO, costs were estimated to be $11.6 million; costs for a medium ACO were estimated to be $26.1 million.**

Table 1: Estimates of ACO Start-up and Ongoing Costs for Year 1

Estimate of ACO Investment	Average
CMS (based on a range of 75 to 150 ACOs)	$1,800,000
McManis (200-bed, single hospital system with 80 primary care physicians and 150 specialists)	$11,600,000
McManis (1200-bed, five-hospital system with 250 primary care physicians and 500 specialists)	$26,100,000

Note: McManis Consulting's estimates are based on case studies and include start-up and ongoing costs for a typical year. Some costs already may have been incurred or be allocable to other budgets.

[1] www.aha.org/ACOcasestudies

We ask CMS to consider also offering grant money in specific areas to offset the extensive investment that is needed. It is unlikely that an ACO, especially those with smaller numbers of aligned beneficiaries, will earn the amounts suggested above through the shared savings bonus. Therefore, each potential ACO will need access to capital in different areas depending on the organization. We recommend that CMS establish grant mechanisms through the Innovation Center in the dimensions listed in Appendix A. For example, costs under dimension 11 – care coordination and discharge management for a small ACO – is estimated to be $1 million on an ongoing basis and $3 million for medium ACO. We encourage CMS to make grants available for testing innovative care coordination and discharge management strategies that offset all or a portion of these ongoing costs. Further, we encourage CMS to align these grant opportunities with other initiatives underway in the Innovation Center, including the *Partnership for Patients* and the *Community Care Transitions Program*.

While we believe that advance payments and/or grants could help organizations address the infrastructure development costs for certain ACOs, it would not replace the need for major changes to the MSSP in the final rule. An advance payment program and grants could make the MSSP more attractive, but significant improvements to the rule, such as those recommended in the AHA's MSSP comment letter, are necessary to make the program attractive and operationally viable.

The AHA strongly supports the delivery of accountable care, and we appreciate the Innovation Center's proposal to implement the Advance Payment Initiative as a way to increase participation in the MSSP. Thank you for your consideration of our suggestions. If you have any questions, please contact Lisa Grabert, senior associate director of policy, at (202) 626-2305 or lgrabert@aha.org.

Sincerely,

/s/

Linda E. Fishman
Senior Vice President, Public Policy Analysis & Development

Attachment

Attachment: ACO-like Activities and Costs

SUMMARY: ACTIVITIES AND COSTS TO ESTABLISH AN ACO-LIKE ORGANIZATION

	Prototype A: (200 bed, 1-hospital system 80 PCPs, 150 specialists)		Prototype B: (1,200 bed, 5-hospital system, 250 PCPs, 500 specialists)	
Activity	**Start up Costs**	**Ongoing (Annual) Costs**	**Start up Costs**	**Ongoing (Annual) Costs**
Group I. Network Development and Management				
1. Providing ACO management and staff	$550,000	$1,150,000	$600,000	$3,200,000
2. Leveraging the health system's management resources	$250,000	$200,000	$300,000	$250,000
3. Engaging legal and consulting support	$350,000	$125,000	$500,000	$125,000
4. Developing financial and management information support systems	$500,000	$80,000	$500,000	$160,000
5. Recruiting/acquiring primary care professionals, right sizing practices	$400,000	$800,000	$800,000	1,600,000
6. Developing and managing relationships with specialists	*	*	*	*
7. Developing and managing an effective post-acute care network	*	*	*	*
8. Developing contracting capabilities	$150,000	$150,000	$150,000	$150,000
9. Compensating physician leaders	$75,000	$75,000	$190,000	$190,000
Group II. Care Coordination, Quality Improvement and Utilization Management				
10. Disease registries	$75,000	$10,000	$150,000	$20,000
11. Care coordination and discharge follow-up	$150,000	$1,000,000	$300,000	$3,000,000
12. Specialty-specific disease management	–	$150,000		$300,000
13. Hospitalists	$80,000	$160,000	$160,000	$320,000
14. Integration of inpatient and ambulatory approaches in service lines	*	*	*	*
15. Patient education and support	–	$100,000	–	$100,000
16. Medication management	–	$100,000	–	$100,000
17. Achieving designation as a patient-centered medical home	$100,000	$15,000	$150,000	$25,000
Group III. Clinical Information Systems				
18. Electronic health record (EHR)	$2,000,000	$1,200,000	$7,050,000	$3,500,000
19. Intra-system EHR interoperability (hospitals, medical practices, other)	$200,000	$200,000	$400,000	$200,000
20. Linking to a health information exchange (I IIC)	$150,000	$100,000	$200,000	$200,000
Group IV. Data Analytics				
21. Analysis of care patterns	$210,000	$210,000	$450,000	$450,000
22. Quality reporting costs	$75,000	$75,000	$100,000	$100,000
23. Other activities and costs	–	$100,000	–	$100,000
TOTAL	**$5,315,000**	**$6,300,000**	**$12,000,000**	**$14,090,000**

**Costs are primarily management and staff and are included in previous elements (1,2 and 3).*

AMA AMERICAN MEDICAL ASSOCIATION

Michael D. Maves, MD, MBA, Executive Vice President, CEO

June 16, 2011

Richard J. Gilfillan, MD
Acting Director
Center for Medicare and Medicaid Innovation
Centers for Medicare and Medicaid Services
7500 Security Boulevard, C5-15-12
Baltimore, MD 21244

Subject: Advance Payment Initiative

Dear Dr. Gilfillan:

On behalf of the physician and medical student members of the American Medical Association (AMA), we appreciate the opportunity to provide input on the concept of an Advance Payment Initiative for Accountable Care Organizations (ACOs) entering the Medicare Shared Savings Program (MSSP). We commend the Centers for Medicare and Medicaid Services (CMS) and the Innovation Center for exploring ways to assist physicians and other health care providers to obtain the resources and support they need to successfully create and implement ACOs, and we also commend you for seeking input on these concepts before they are finalized and announced.

Before providing our suggestions, we must note that because of the uncertainty about what will be included in the final regulations for the MSSP, it is difficult to provide definitive input on any initiative that is designed to facilitate physician participation in the MSSP. As we explained in detail in the comments we submitted earlier this month on the Notice of Proposed Rulemaking, many of the requirements CMS has proposed for ACOs are very burdensome and will make it difficult, if not impossible, for many physicians to form ACOs or participate in them. An Advance Payment Initiative could help to mitigate some of those problems, but whether such an initiative can be successful in facilitating broader participation in the MSSP will inherently depend on the details of how the final ACO regulations are structured.

The AMA believes there is a clear need for CMS to make changes upfront in the way ACO physicians are paid in order for the MSSP to be successful. There are at least five fundamental problems which create this need:

1. For some patients, physicians may conclude that a patient will benefit by *shifting* the care a patient receives from services that are currently reimbursable under the Medicare Physician Fee Schedule to services which are not. Doing so, however, would obviously cause them to lose money in the short run. Today, physicians are not paid by Medicare for many types of care that are very desirable for patients and may be more cost-effective than some of the services that Medicare does cover. For example, under Medicare's current payment system, a physician can be paid for seeing a patient in

the office, but not for telephone or online evaluation and management services. This means that if a telephone consultation would more promptly and conveniently address a patient's health needs than would an office visit, a physician who speaks to the patient on the telephone rather than asking them to come to the office will lose money. Yet, there would be no increase in cost to Medicare if it paid for the telephone conversation, because it would simply substitute for a different reimbursable service, and the patient would clearly benefit.

2. Physicians may conclude that a patient will benefit if the physician practice provides *additional* services that are currently unreimbursable but which can reduce expenditures elsewhere in the health care system. The costs of providing these additional, unreimbursed services will cause the physician practice to lose money, at least in the short term. For example, numerous studies have shown that patients with chronic diseases can benefit significantly from having a nurse care manager visit them in their home or talk to them over the phone to ensure they understand how to manage their condition, take their medications, and respond to problems. Patients receiving this kind of assistance are much less likely to need to go the emergency room or to be admitted or readmitted to the hospital, saving Medicare far more than the cost of hiring the nurse, but since care management services are not covered, the costs of hiring the nurse would cause the practice's net revenues to decline.

3. If, through the provision of higher quality, more coordinated care, physicians keep their patients healthier, they are likely to reduce their patients' need for covered Medicare physician services. This could cause physician practice revenues to fall, at least in the short run. For example, if the chronic disease patients discussed above have their health needs addressed more quickly and effectively through prompt telephone discussions with their physician and education from a nurse care manager, the patient may experience fewer problems and need to see the physician less often.

4. The extensive requirements which the proposed rules suggest that CMS will impose on ACOs under the MSSP, such as measuring and reporting on a large number of quality metrics and installing electronic health record systems, will force physicians to incur significant unreimbursed administrative costs, which could cause their practices to lost money, at least in the short run.

5. In theory, the "shared savings" payments that CMS will be making to ACOs could offset these losses, although any such offsets will be delayed by 18 months or more until after savings are calculated and paid, leaving the physician practice to cover the short-term losses from their own resources. However, even when shared savings payments are made, they may fall far short of the costs physicians actually incurred, not because total expenditures have not declined, but because of the rules of the shared savings program. For example: (1) even if the improvements in care made by physicians do generate savings for Medicare, some or all of the savings may not be attributed to the physician's ACO (if the patients received a plurality of their primary care from physicians outside of the ACO); (2) total savings generated may be insufficient to meet the minimum threshold for shared savings; or (3) the size of the payment remaining after CMS retains its share may be less than the costs that all ACO participants incurred. Any of these factors could result in physician practices receiving shared savings bonuses that are less than the costs or losses they incurred in order to generate savings for Medicare or simply to participate in the ACO.

These problems are not unique to physician practices; for example, hospitals which create programs designed to reduce readmissions will lose more revenue from fewer admissions than they save through the avoided costs of those admissions, thereby reducing their operating margins. However, physician practices, particularly small physician practices, are the least likely of any health care provider to have

capital reserves or access to other sources of capital that could enable them to "float" these costs until some or all of them can be covered with shared savings payments.

Paying Physician Practices for Non-covered Services

The most effective way to address Problems 1 and 2 above is for Medicare to pay physician practices for three key types of services that can help them make care more patient-centered, coordinated, and efficient:

- Non-face-to-face communications between physicians and patients, such as telephone calls and electronic mail;
- Patient education and care management services by physicians and other health professionals;
- Phone consultations between primary care and specialist physicians to enable the primary care team to tap the expertise of the specialty physician without requiring a face-to-face visit between the specialist and patient.

There are CPT codes for several of these services with relative value units assigned to them, but telephone and online consultations, care management, patient education and team conferences need to be authorized for Medicare payment. Covering these services as they are delivered would not only eliminate short term cash flow problems for the physician practice, but also protect the practice from receiving too small a portion of any "shared savings" payments that are ultimately paid to the ACO.

The AMA believes that, from both physicians' and Medicare's perspective, paying for these specific services would be preferable to trying to cover them through a monthly per patient payment. Reimbursing for the particular services ensures that each physician practice will be compensated for as many or few cases in which these changes would be made, rather than having a fixed monthly payment that may be too low or too high for the needs of a particular physician practice's patients. The service-specific approach also allows the specific types of services to be tracked more accurately by both the physician practice and Medicare, and would make it possible to evaluate whether these payment changes should be extended more broadly.

In addition, the AMA recommends that CMS offer physician practices the option of receiving a monthly per-patient payment instead of service-specific payments. Some physician practices and ACOs may already be moving away from fee-for-service payment in their contracts with other payers, such as private plans or Medicaid, so a monthly per-patient payment, even if it is blended with fee-for-service payments, may be more consistent with the payment models the practices have with other payers.

Paying Physician Practices a Monthly Care Management Payment

In contrast to Problems 1 and 2, the increased costs and reduced revenues identified in Problems 3 and 4 are not associated with the delivery of specific services to specific patients, so they cannot be addressed through coverage of CPT codes for non-face-to-face services. A portion of the costs associated with Problem 2 also is not directly associated with specific services to specific patients, or may vary from the standard relative value calculation for the associated CPT code; for example, a nurse care manager working with a small but complex chronic disease population will likely need to spend more time with each patient on average than with lower-acuity patients and also spend more time tracking and analyzing patient care using a patient registry and other tools.

These types of costs are more amenable to being addressed through a monthly "care management" payment to the physician practice based on practice size or number of patients rather than the number of services delivered. Ideally, such payments would be severity-stratified in some way, e.g., with higher amounts paid to practices which have larger numbers of patients with more health conditions and/or more severe conditions.

We do not believe that any single, one-size-fits-all monthly amount should be offered by CMS. We recommend that each ACO be permitted to define the amount of payment that it feels it needs in order to cover the costs of the specific care changes it plans to implement and the administrative costs it expects to incur to meet requirements imposed by CMS. This will ensure that CMS pays no more than necessary, but that the ACO receives no less than it will need to be successful.

Eliminating Expensive, Unnecessary Requirements

Some of the need for upfront money to address Problem 4 can be reduced by eliminating unnecessary requirements in the MSSP or modifying them so they are less burdensome. For example, there is no justification for requiring that at least 50 percent of an ACO's primary care physicians be "meaningful users" of electronic health records (EHR) by the second year of the ACO program. ACO physicians can change the way care is delivered before installing EHR systems. To the extent that the EHR requirement does not deter physician practices from participating at all, it will impose significant costs on them without any guarantee of higher savings to offset those costs. The costs are not just the purchase of the EHR software and equipment, but the loss in physician and staff productivity that routinely accompanies EHR installation, particularly in the short run.

In addition, we would urge CMS to look beyond the MSSP requirements and reduce or eliminate other unnecessary and burdensome requirements in the Medicare program. The vast majority of physicians are honest people who want to take care of patients and have little time to waste on unnecessary administrative details. Many physicians have identified Medicare documentation requirements as a major imposition that delays care with redundant requirements for verifying physician orders and voluminous medical records where the salient patient information is buried in reams of purposeless, formulaic language. To make matters worse, besides requiring physicians to over-document what they themselves do, physicians are also expected to keep other providers honest by certifying and recertifying the need for virtually any other service the patient requires—from power wheelchairs, to repeat orders of glucose strips or diapers for patients with chronic ongoing conditions, to physical therapy plans, home health and hospice services. Once a patient has a debilitating disease that cannot be cured, physicians should not be required to recertify their need for services or supplies that they will need for the rest of their lives. For example, CMS should reexamine its policies for recertifying orders for blood glucose testing strips and diapers for patients with chronic ongoing conditions.

Providing Loans and/or Loan Guarantees

In addition to establishing a payment mechanism that can finance the ongoing investment required, it is important to recognize that many physician practices will need to make significant upfront investments in new equipment, software, or even new facilities to better manage patient care and reduce costs elsewhere in the health care system. For example, if CMS enables physicians to be more responsive to patient phone calls or electronic mail by paying them for phone and email interactions as recommended earlier, the practice may need to install a more sophisticated telephone system or a secure electronic mail or patient web portal to support these services. Although the costs of such investments could be recovered

over time through the individual service and shared savings payments the physician practice receives, the practice will still need to have the initial capital to make the investments.

Although commercial lenders are a potential source of such capital, it may be difficult for small, independent physician practices to convince commercial lenders that these are sound investments, particularly since the payment model for ACOs will be so different than the way other physician practices are compensated. Consequently, the AMA recommends that CMS either create a loan program to directly help physicians finance these investments, or create a loan guarantee program, similar to the Small Business Administration's successful 7(a) program for small businesses, that would encourage commercial lenders to provide this kind of financing.

We also recommend that a provision be included in such a program to forgive the loans if the shared savings program does not continue, or if a physician practice or ACO is forced to withdraw from the program because new requirements added in the future make it financially impossible for them to continue. A physician practice should not be left without a means of paying for investments that it made in a good faith to participate and succeed in this new and inherently experimental program.

Sharing More Savings, and Sooner

The need for upfront money can also be reduced simply by making the rules for calculating and distributing shared savings reflect a more balanced partnership between CMS and the ACO. As noted in our comments on the MSSP and listed below, the proposed rule makes it extremely difficult for ACOs, particularly small ACOs, to obtain shared savings:

1) Under the proposed rule, the ACO must achieve a minimum percentage savings in order to prove that the savings are not "random," and the percentages are very high for small ACOs.
2) Except for the smallest ACOs, CMS keeps the first two percent of any savings that are generated before the ACO is eligible for any share of the savings.
3) CMS shares at most 50 to 60 percent of the savings beyond that two percent.
4) The savings percentage is reduced based on an ACO's performance against quality standards that have not yet been defined.
5) The savings that an ACO can receive is capped at 7.5 percent to 10 percent of the baseline expenditure.
6) Twenty-five percent of the savings share that ACOs do qualify for is retained by CMS as a hedge against the need for the ACO to pay CMS for cost increases in future years.
7) The savings share is not paid until a year after the end of the year in which the savings are actually achieved.
8) Not all patients for which the ACO achieved savings may be attributed to the ACO, and conversely, the ACO may be held accountable for some patients who only used the ACO for a small portion of their total services during the year.

CMS can address these issues and reduce an ACO's need for upfront payment by: (1) reducing the thresholds for qualifying for shared savings; (2) allowing sharing of the first dollar of savings for larger ACOs; (3) sharing a higher percentage of savings, at least in the early years of the program; (4) setting a minimum percentage of savings that will be distributed regardless of the ACO's performance on quality metrics; (5) eliminating the cap on the amount of savings that can be shared; (6) eliminating the 25 percent withhold; (7) calculating and paying shared savings more quickly; and (8) eliminating the use of retrospective attribution and allowing ACOs to take accountability for patients who voluntary agree to be part of the ACO.

Unless a physician practice is receiving an upfront global or capitation payment, however, even paying a bigger share of savings faster does not eliminate the need for upfront money entirely. The provision of higher quality services can only affect downstream costs, so any savings will inherently follow the upstream investments made to improve quality, and Problems 1-4 identified earlier will persist to some extent. Consequently, we recommend that CMS offer advance payments to ACOs regardless of how CMS defines the rules for calculating and distributing shared savings.

We appreciate the opportunity to provide this input. The AMA would be pleased to provide additional information that would be helpful and work with you to implement these recommendations.

Sincerely,

Michael D. Maves, MD, MBA

June 17, 2011

Richard J. Gilfillan, M.D.
Director
Center for Medicare and Medicaid Innovation
Centers for Medicare and Medicaid Services
200 Independence Ave. S.W.
Washington, DC 20201

Submitted electronically

RE: Advance Payment Initiative for ACOs Entering the Medicare Shared Savings Program (Section 3022 of the Affordable Care Act)

Dear Dr. Gilfillan:

On behalf of the over 78,000 member physical therapists, physical therapist assistants, and students of physical therapy of the American Physical Therapy Association (APTA), I would like to submit the following comments regarding the Advance Payment Initiative for Accountable Care Organizations (ACOs) entering the Medicare Shared Savings Program (MSSP). First, APTA would like to applaud the Center for Medicare and Medicaid Innovation (CMMI) for taking an important step toward increasing participation in this new integrated care delivery system that strives to be interdisciplinary, patient-centered, and seeks to improve the quality of care for Medicare beneficiaries throughout the health care continuum. We look forward to working with both CMMI and the Centers for Medicare and Medicaid Services (CMS) throughout the process of implementing the MSSP.

APTA is pleased that CMMI recognizes that the start-up costs for ACO implementation will be significant for ACO professionals. In fact, it is estimated that start-up costs can range from $11.6 million to $26.1 million to launch an ACO and manage it for the first year[1] and it may take some time for the ACOs to see a return of investment. We appreciate the effort from CMMI to mitigate the burden of start-up costs for ACO professionals through the Advance Payment Initiative. However, we fear that this funding may not reach ACO participants, such as physical therapists, who will need assistance with significant start-up costs as well.

Advance payment would be helpful for ACO participants, as ACOs may look to their ACO participants and ACO providers/suppliers to bear some of the start-up costs in order to be a part of the ACO. In addition, APTA strongly believes that the participation of physical therapists in

[1] American Hospital Association and McManis Consulting. The Work Ahead: Activities and Costs to Develop an Accountable Care Organization (April 2011).

an ACO electronic health record (EHR) is vital to the success of the ACO. This will require appropriate resources and support to be furnished under the MSSP for physical therapists to adopt interoperable EHRs that are necessary to communicate and coordinate care with other ACO participants and professionals**.** Smaller ACO participants, such as physical therapists in private practice, are not prepared to assume the financial burden to adopt such systems. Therefore, we strongly encourage CMMI to include funding for participants, or, at the very least, require ACO professionals to include a mechanism to share the advance payments with participants within the ACO's plan for using these advance funds.

In closing, APTA thanks CMMI for the opportunity to provide comments on the Advance Payment Initiative. Physical therapists are committed to providing quality care to Medicare beneficiaries through integrated models of care such as ACOs and achieving the three-part aim of health care reform, which is to provide better care to individuals, better health for populations, and to lower growth in expenditures. APTA looks forward to working with CMS and CMMI to ensure that physical therapists who wish to participate in ACOs have the resources to participate. If you need additional information or have questions regarding our comments, please contact Roshunda Drummond-Dye at (703) 706-8547 or roshundadrummond-dye@apta.org.

Sincerely,

R. Scott Ward, PT, Ph.D.
President

RSW: rdd

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June 17, 2011

Donald Berwick, MD, MPP, FRCP
Administrator
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Washington, DC 20201

RE: Advance Payment Initiative for ACOs entering the Medicare Shared Savings Program (Sec. 3022 of the Affordable Care Act)

Submitted electronically: advpayACO@cms.hhs.gov

Dear Dr. Berwick:

AHIP appreciates the opportunity to comment on the Center for Medicare & Medicaid Innovation's proposed Advance Payment Initiative (API) for eligible ACOs entering the Medicare Shared Savings Program. We recognize that some provider organizations have expressed concern regarding anticipated start-up costs and their ability to access capital to invest in the necessary infrastructure and personnel for care coordination under the Shared Savings Program. By allowing eligible ACOs to receive an advance on their anticipated future shared savings in the form of a monthly per-beneficiary payment, the Center proposes to test how this pre-payment could impact participation in the Shared Savings Program.

We support the establishment of the Shared Savings Program, designed to reduce fragmentation of care delivery and align incentives to encourage the provision of better, safer and more cost-effective health care services. While some provider organizations, especially practices with one to four physicians, may have difficulty accessing capital to reengineer their office practices to meet the goals of the Shared Savings Program, we encourage the Center to look to private sector accountable care models and capitalization strategies to build on progress already being realized and promote greater alignment across public and private programs. In addition, the Small Business Administration (SBA) offers a number of loan programs that make it easier for small businesses to obtain financial support. These loans, typically community-based, may be available to small physician practices.

Partnerships with health plans have been instrumental in enabling physician groups to access the tools and resources necessary to better coordinate care, enhance decision support at the point of care and exchange key health information to improve care transitions from one setting to another. Additionally, depending on the level of readiness of physician practices to assume

accountability for population management, some of our member plans assist physician organizations, particularly small physician groups, in meeting capitalization and information technology (IT) infrastructure requirements.

We urge the Center to encourage participation in the Shared Savings Program and alignment with the private sector by first providing opportunities for similar partnerships in the Program. Specifically, as we noted in our June 6, 2011 comment letter in response to the Medicare Shared Savings Program Notice of Proposed Rulemaking (NPRM), CMS should allow for the participation of health plans as investors in and/or partners of ACOs by reducing the minimum threshold of participant control of an ACO's governing body. The current proposal to set the minimum threshold of participant control at 75% may discourage support by health plans and others as investors and partners in these organizations, potentially resulting in less diversity of participating ACOs. In doing so, the current proposal is likely to deter the types of partnerships in Medicare that are otherwise evolving in the private sector.

Existing SBA loan programs provide another option for provider organizations seeking to start or expand a small business. These loan programs assist small businesses in obtaining financing from commercial lenders and include programs that specifically target businesses that operate in rural areas and underserved communities. The SBA-backed loans can be used for a variety of purposes, including start-up and expansion costs, working capital, and fixed assets, such as medical equipment.

In its announcement of the API, the Center noted that ACOs would have to meet "organizational criteria" in order to be eligible for the advanced payments and would be required to provide a plan to use the funds "to build care coordination capabilities."[1] We believe that a properly structured advance payment program should: (1) direct funds to eligible provider organizations that demonstrate need; and (2) target the use of funds for key infrastructure development to enable a greater number and range of provider organizations to participate in the Shared Savings Program.

To have the greatest impact on participation in the Shared Savings Program, advance payments should be limited to ACOs that are: (1) small, physician-led ACOs seeking to vertically integrate but lack adequate capital; or (2) ACOs in underserved areas that function as safety net providers. Typically, the presence of a robust infrastructure is driven by the size of the provider organization as larger organizations may have greater access to capital markets. As such, smaller physician groups unaffiliated with hospital systems may have less access to the financial capital needed to invest in information technology and redesign processes of patient care. Likewise, ACOs that function as safety net providers in underserved areas may have similar access challenges that may preclude them from successfully participating in the Shared Savings Program. To be eligible for an advance payment, small physician-led and safety net practices

[1] http://innovations/cms.gov/areas-of-focus/seamless-and-coordinated-care-models/advance-payment/

should also be required to demonstrate that they can meet the key elements to participate in the Shared Savings Program, including leadership, the commitment to redesign care processes, improve existing infrastructures, and expand access.

To target key infrastructure outlays that are most integral to care coordination functions, advance payments should be limited to: (1) development of a health information technology infrastructure that allows for information exchange; (2) employment of non-physician personnel for case management and management of care transitions; and (3) integration of community services to meet the needs of an ACO's beneficiary population. These key infrastructure components not only are likely to represent a significant portion of an ACO's start-up investment and first year operating expenditures, but also are likely to have the greatest impact on quality improvement and improved patient outcomes that can help an ACO meet the shared savings goals.

Lastly, the Center should consider a contingency plan for recouping advance payments in the event that an ACO that receives an advance payment does not achieve shared savings. While the Shared Savings Program includes numerous safeguards to ensure repayment of shared losses, implementation of the API has the potential to expose ACOs to even greater financial liability that may not be sufficiently addressed by the proposed safeguards.

Thank you for the opportunity to comment on the API. We appreciate your leadership in promoting programs and initiatives designed to improve the quality and efficiency of the health care system. We look forward to a continued dialogue on the important role health plans are playing in private sector reforms and how a comparable role in public programs can advance the goals of the Shared Savings Program.

Sincerely,

Carmella Bocchino

Carmella Bocchino
Executive Vice President
Clinical Affairs and Strategic Planning

June 13, 2011

Dr. Richard Gilfillan
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7500 Security Blvd.
Baltimore, MD 21244

Re: CAPG comments for Medicare Shared Savings Program (MSSP)

Dear Dr. Gilfillan,

On behalf of the California Association of Physician Groups (CAPG), we are writing to provide comments on the Center for Medicare and Medicaid Innovation's (CMMI or Innovation Center) request for suggestions regarding potentially pre-paying a portion of future shared savings for participants in the Medicare Shared Savings Program (MSSP).

CAPG represents over 150 California multi-specialty medical groups and independent practice associations (IPAs). Our members serve over 15 million Californians, who comprise approximately one half of the state's insured population. Our patient base is larger than the total population of most other states. CAPG members provide comprehensive health care through coordinated, accountable, physician group practices. We strongly believe that patient-centered, coordinated, accountable care offers the highest quality, the most efficient delivery mechanism and the greatest value for patients. California physicians, including CAPG members, have operated under this accountable, budget-responsible model for over 25 years.

Based on this considerable experience, CAPG believes that the existing Medicare payment system does not go far enough to encourage the appropriate care for the patient every time, and instead rewards providers for the quantity of care they deliver. The Affordable Care Act (ACA), through a series of pilots and demonstrations, seeks to reform the way we provide care in the United States. In particular, the MSSP and the initiatives that will be undertaken by the CMMI, are key aspects of accomplishing this goal of delivery system reform.

However, we believe that there are certain costs that even providers with substantial care coordination experience will face in preparing to participate in the shared savings program. Numerous stakeholders have identified significant potential costs associated with the MSSP –

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including hiring new staff, communicating with beneficiaries, programming new quality measures, and so on. In order to succeed in achieving savings for Medicare, ACOs must have the capital to invest in care coordination, disease management, and health information technology.

To foster increased participation in the MSSP, CAPG supports the creation of an Advance Payment program. CAPG recommends setting the advance payment rate at three percent of an ACO's benchmark. The ACO would receive 40 percent of the payment at the start of the first performance year and the remaining 60 percent would be distributed in equal quarterly installments throughout the remainder of that performance year. At the end of the performance year, any differences between the amount paid up front and the ultimate shared savings achieved would be reconciled.

Providing access to up front funding will enable ACOs to make investments in the types of programs and infrastructure that are critical to building coordinated care models, such as disease registries and health information technology systems. Through our experience we have learned that these programs are critical to the success of coordinated care. We look forward to the Innovation Center's proposal.

Sincerely,

DONALD H. CRANE
President & CEO
California Association of Physician Groups

CATHOLIC HEALTH INITIATIVES®

A spirit of innovation, a legacy of care.

198 Inverness Drive West
Englewood, CO 80112

Phone 303.298.9100
Fax 303.298.9690

June 16, 2011

Richard Gilfillan, M.D.
Acting Director
Center for Medicare and Medicaid Innovation
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted electronically to advpayACO@cms.hhs.gov

Re: Advance Payment Initiative for Accountable Care Organizations entering the Medicare Shared Savings Program

Dear Dr. Gilfillan,

Catholic Health Initiatives (CHI) appreciates the opportunity to provide comments on the Center for Medicare and Medicaid Innovation's (Innovation Center) advance payment initiative for Accountable Care Organizations (ACOs) participating in the Medicare Shared Savings Program (MSSP). CHI is a faith-based, mission-driven health system that includes 72 hospitals; 40 long-term care, assisted living, and residential units; two community health service organizations; and numerous physician practices and home health services across 19 states.

The advance payment option will provide much-needed support as providers seek to form ACOs, but will not be enough to encourage participation in the MSSP unless significant changes are made to the rule itself. CHI offered numerous recommendations to the Center for Medicare and Medicaid Services (CMS) to address concerns we have with the MSSP and ACO proposed rule. While we appreciate CMS' interpretation of many of the ACO provisions, there are far too many unanswered questions and glaring omissions to make the proposed ACO rule workable for the majority of providers.

We applaud the Innovation Center for recognizing that many providers who may wish to participate in the MSSP will not have the up-front capital available to do so. However, providing funds to create an ACO that will participate in a flawed MSSP is solving only one part of the equation. CMS must address the problems in the ACO proposed rule—including overly prescriptive requirements, retrospective assignment of beneficiaries, confusing quality standards with unrealistic timetables, and low shared savings potential—to make the MSSP attractive and financially feasible for providers. Only then can the Innovation Center's advance payment initiative help providers realize the goal of improving quality and reducing overspending in the Medicare program through ACOs and the MSSP.

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Recommendation: CHI commends the Innovation Center for its understanding of the financial difficulty many providers will face forming and operating an ACO. Providing financial start-up assistance will be invaluable to many providers who would be unable to start an ACO without the Innovation Center's advance payment initiative. However, we urge the Innovation Center to encourage CMS to include many of the recommendations of the public in the final ACO and MSSP final rule to ensure that any advanced payment funds provided by the Innovation Center will go to ACOs that are participating in an operationally viable shared savings program.

Thank you. If you need additional information, please contact me at 303-383-2693.

Sincerely,

Colleen Scanlon

Colleen Scanlon, RN, JD
Senior Vice President, Advocacy

ACO Development Project - Innovation Center - Advanced Payment Initiative Cost Estimates

Estimated Overhead, Technology, Management and Clinical Expenses

CSMS-IPA, Inc. - 2011

Expense category		Months	$ per Month in Year 1	Year 1 Total Expense	Start Up Costs (3)	Ongoing Annual Expenses	Ongoing Exp as % of Yr. 1
Project Consulting		12	20,000	240,000	80,000	180,000	75%
HIT Development	Tech Consulting	12	8,000	96,000	32,000	72,000	75%
	Practice Support + Registries	12	6,000	72,000	24,000	54,000	75%
	Quality reporting	12	3,000	36,000	12,000	27,000	75%
	Clinical Decision Support (5)	12	1,000	12,000	-	2,400	20%
	ETG/Bundling/Pred Model	12	4,000	48,000	16,000	9,600	20%
	Local HIE Development	12	5,000	60,000	20,000	45,000	75%
Management Infrastructure	Executive Director	12	15,625	187,500	62,500	187,500	100%
	Analytics Staff	12	10,000	120,000	40,000	120,000	100%
	Administrative Coordinator	12	4,688	56,250	18,750	56,250	100%
	Process Engineer	12	10,417	125,000	41,667	125,000	100%
	Patient/Prov Satisfaction	12	2,500	30,000	-	30,000	100%
	Office space	12	2,000	24,000	8,000	24,000	100%
Clinical Infrastructure	Medical Director	12	13,021	156,250	52,083	156,250	100%
	Physician Leadership Training	12	2,000	24,000	8,000	24,000	100%
	Committees	12	2,500	30,000	10,000	30,000	100%
	Primary Care pmpm (4)	12	75,000	900,000	-	900,000	100%
	Pharmacist	12	10,417	125,000	41,667	125,000	100%
	Behavioral Health Specialist	12	7,813	93,750	31,250	93,750	100%
	Care Coordination	12	68,750	825,000	275,000	825,000	100%
				3,260,750	772,917	3,086,750	95%
Estimated PMPM				**$27.17**		**$25.72**	
Estimated PMPM for Start up through first 12 months					**$33.61**		

	# of Positions	Salary	Ben	Total	Per Month
Executive Director	1	$ 150,000	25%	$ 187,500	$ 15,625
Medical Director (1)	1	$ 125,000	25%	$ 156,250	$ 13,021
Administrative Coordinator	1	$ 45,000	25%	$ 56,250	$ 4,688
Care Coordination(2)	12	$ 55,000	25%	$ 825,000	$ 68,750
Pharmacist	1	$ 100,000	25%	$ 125,000	$ 10,417
Behavioral Health	1	$ 75,000	25%	$ 93,750	$ 7,813
Process Engineer	1	$ 100,000	25%	$ 125,000	$ 10,417

Notes to Projections

(1) Part time (1/2 FTE)

(2) One Professional FTE per 750 beneficiaries

(3) Estimated 4 months of pre-commencement work

(4) PMPM Payment to PCP Practices based on attributed beneficiaries	$7.50	pmpm
(5) CDS application to control High End Imaging Services - RadPort	$0.10	pmpm

Model Assumptions

Number of Attributed Beneficiaries	10,000
Projected monthly beneficiary expenses in model	$700.00
Total Annual Projected Spend	$ 84,000,000

Results of Projected Expenses over Projected Spend

% of Shared Savings needed to cover Start Up + Year 1 Estimates	**4.80%**
% of Shared Savings needed to cover Ongoing Annual Cost Estimates	**3.67%**

ROI Projections

			Cumulative ROI
Assuming a Surplus Margin (Future Shared Savings) against projected costs annually of		4.50%	
Percentage Increase/Decrease from projection in year	1	-0.30%	-0.30%
Percentage Increase/Decrease from projection in year	2	0.83%	0.52%
Percentage Increase/Decrease from projection in year	3	0.83%	1.35%
Percentage Increase/Decrease from projection in year	4	0.83%	2.17%
Percentage Increase/Decrease from projection in year	5	0.83%	3.00%

This will not work!

Everytime a test or treatment is denied to a Medicare recipient, he/she will blame this flawed scheme. Give the money saved to patients rather than to the government or to doctors.

David K. Cundiff

The Innovation Center is considering an Advance Payment Initiative for those ACOs entering the Medicare Shared Savings Program

Dear sir
the entire affair has been very challenging and extremly time consuming
already consumed time and more to go
question folks have is
is it worth when no one is sure whether funds will come or not and when
I think the best way to do is to give each doctor certain amount of funds as abonus or stmulus money as was given to banks and car industry and have them comply

Innovative centers should also fund for innovations which wil reduce technical errors and ther by improve the quality and reduce cost

Too much paper work and looks like only who gets the benfit form inoovations are close to or that is the perceptions
since you asked I am providing this info
than
dinesh

Dr. Dinesh Patel, M.D.
Chief of Arthroscopic Surgery
Associate Clinical Professor
Harvard Medical School
Massachusetts General Hospital

HANYS Healthcare Association of New York State

Proud to serve New York State's Not-For-Profit Hospitals, Health Systems, and Continuing Care Providers

Daniel Sisto, President

June 17, 2011

Richard Gilfillan, M.D.
Acting Director
Center for Medicare and Medicaid Innovation
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Re: Advance Payment Initiative for Accountable Care Organizations entering the Medicare Shared Savings Program

Dear Director Gilfillan:

The Healthcare Association of New York State (HANYS), the only statewide hospital and continuing care association in New York, representing more than 550 non-profit and public hospitals, nursing homes, home care agencies, and other health care organizations, submits these comments in response to the Innovation Center's request for comments on its proposed *Advance Payment Initiative for Accountable Care Organizations (ACOs) entering the Medicare Shared Savings Program (SSP).*

Under the proposed initiative, eligible ACOs participating in the SSP could receive a monthly payment from the Innovation Center for each aligned Medicare fee-for-service beneficiary as an advance on the shared savings they are expected to earn from participation in the program. As we understand it, such payments would be reserved for investment in the staff and infrastructure needed to enhance care coordination capabilities.

HANYS commends the Innovation Center for proposing this creative funding solution. Many of New York's non-profit hospitals and health systems are interested in forming ACOs but simply do not have the access to capital necessary to finance participation in the SSP. Indeed, we previously noted in our June 6, 2011 comment letter on the SSP to Donald Berwick, Administrator, Centers for Medicare and Medicaid Services (enclosed), that advance payments must be made available to encourage ACOs to participate in the SSP since substantial upfront investments are required.

We believe that the proposed *Advance Payment Initiative* is a step in the right direction but that the use of funds distributed under the *Advance Payment Initiative* should be as flexible as possible given the sizable investment and operating costs for ACOs participating in the SSP.

For example, hospital-based ACOs will need to devote substantial resources to expand their primary care provider networks and increase utilization management activities. Additionally, ACOs will need to make costly investments in their information technology systems and implement evidence based medicine protocols to deliver higher quality, more efficient patient-centered care. Expanding the scope of acceptable use of advance payment funds will help ACOs to remain financially solvent while they transition their operations to align with the goals of the SSP.

Thank you for providing HANYS *with* this opportunity to comment on the *Advance Payment Initiative*. If you have any questions about our comments, please contact me at (518) 431-7681.

Sincerely,

Jeffrey Gold
Vice President, Managed Care and Special Counsel

JG/dd

Enclosures: (1)

MAIN HEADQUARTERS: One Empire Drive / Rensselaer, New York 12144 / (518) 431-7600 / fax (518) 431-7915 / www.hanys.org
WASHINGTON, D.C. OFFICE: 499 South Capitol Street SW, Suite 405 / Washington, D.C. 20003 / (202) 488-1272 / fax (202) 488-1274

1) If the ACO shared savings model is assigning patient retrospectively how is an ACO to anticipate whether or not the patients in their group will be compliant and allow the ACO to provide the proper levels of care.
2) If the intent of the program is to save the Medicare Program money by reducing the amount paid by Medicare for healthcare – does this not mean that the Physicians and Hospitals will be making less money, and any shared savings they would receive would not be equal to the amounts they would have made had they not participated with the program and just billed fee for service as individuals. What is the motivation/incentive for Physicians to participate?

Thank you for addressing these issues.

Terri Goldman
Director of Contracting
Compliance Officer
Home Health Depot

Dear Dr. Gilfillan,

On a recent call with members of the Network for Regional Healthcare Improvement (NRHI), Mai Pham encouraged participants to suggest ways in which the Center for Medicare and Medicaid Innovation (CMMI) can determine which ACOs participating in the Medicare Shared Savings Program (MSSP) should receive advanced payments of future shared savings in order to increase program participation. The Integrated Healthcare Association (IHA) supports this effort to promote broader participation in the MSSP, which will ideally engender participation from ACOs serving populations most in need of coordinated care; below, we offer suggestions based on our experience managing the California Pay for Performance (P4P) Program.

The California P4P Program is the largest non-governmental physician incentive program in the United States. Founded in 2001, this program represents the longest running U.S. example of data aggregation and standardized results reporting across diverse regions and multiple health plans. IHA runs the program on behalf of eight health plans representing 10 million insured persons, and is responsible for collecting data, deploying a common measure set, and reporting results for approximately 35,000 physicians in over 200 physician organizations. These Californian physician organizations are large groups of primary and specialty care physicians who provide care for defined populations of patients; publicly report data on aspects of their clinical and financial performance; are paid on a capitation basis for professional services (and, in some cases, facility services) for their HMO enrollees; and receive incentive payments for performance against a common set of quality and appropriate resource use measures.

Our experience suggests that beyond an organization's financial performance, CMMI should consider the following two objective criteria for allocating advanced payments:

1. Socioeconomic (SES) characteristics of the census tract in which an ACO operates (e.g. median household income; the percent of persons who are unemployed, living below the federal poverty level, employed in working-class occupations, or with less than 12th grade education; and the percent of households with income less than 50% of the median household income). CMMI could employ the widely used measure of area-based SES developed by Dr. Nancy Krieger and her colleagues who worked together on the Public Health Disparities Geocoding Project (Krieger N, et. al. "Painting a truer picture of US socioeconomic and racial/ethnic health inequalities: the Public Health Disparities Geocoding Project." American Journal of Public Health. Feb. 2005 (95.2): 312-23).

2. Payer mix (what percent of an ACO's patients are covered by Medicare, Medicaid, commercial insurance, or are uninsured).

Data from our P4P Program indicate a correlation between SES and performance – physician organizations that are located in lower SES geographies have poorer performance outcomes than those in higher SES regions. Researchers from both RAND and Weill Cornell Medical Center have completed studies analyzing the impact of socioeconomic and geographic factors on physician organization performance using our P4P data, although these studies have yet to be published.

Providers in low SES geographies indicate that they have high proportions of Medicaid and uninsured patients, and are not able to obtain favorable commercial contract payment rates. As a result, they receive lower compensation relative to physician organizations in higher SES geographies, and have less capacity to invest in registries and related HIE, QI staff, primary care providers, and other capabilities that would allow them to succeed under the MSSP.

IHA is enthusiastic about the potential of the MSSP, and believes that the Advanced Payment initiative will be a necessary component of increasing program participation in areas where it is needed most. Results from our work in California suggest that providers in lower SES areas with higher proportions of Medicaid and uninsured patients wishing to form ACOs should be given priority for receiving advanced payment of shared savings, as this would allow them to make essential infrastructure and resource investments upfront, which would increase their chances of succeeding in delivering high-quality, coordinated care.

Sincerely,

Tom Williams, Dr PH, MBA
Executive Director
Integrated Healthcare Association

IOWA HEALTH SYSTEM

Iowa Health System
1200 Pleasant Street
Des Moines, IA 50309
515-241-6161
Fax 515-241-6220

June 16, 2011

Donald M. Berwick, MD, MPP
Administrator
Centers for Medicare and Medicare Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted Electronically to advpayACO@cms.hhs.gov

Re: Advance Payment Initiative for ACOs entering the Medicare Shared Savings Program

Dear Dr. Berwick:

Iowa Health System is pleased to provide the following comments in response to the Advance Payment Initiative for ACOs entering the Medicare Shared Savings Program published as a Request for Comment by the by the Center for Medicare and Medicaid Innovation.

Initially formed in 1995, Iowa Health System (IHS) is Iowa's first and largest integrated healthcare system, serving nearly one of every three patients in the state. IHS is the largest health system in Iowa and western Illinois, with 14 urban affiliate hospitals, 12 network rural hospitals, over 120 physician clinics and numerous home health providers. IHS provides service to over 70 communities in Iowa, eastern Nebraska and western Illinois. In addition, over 2,600 physicians are on the active medical staffs of our facilities. Most recently, the community of Peoria, Illinois joined our health system through our newest affiliate Methodist Medical Center located in Peoria.

Just 10 days ago, we filed comments addressing the proposed rules to the Medicare Shared Savings Program (MSSP), as did health care providers and associations across the country. Although we are not of the same mind as the masses on this point, it has been characterized by media and association publications that the healthcare industry has universally rejected the proposed Medicare Shared Savings Program as a viable option for healthcare providers.

We reiterate our belief that ACOs are the single most promising concept to achieve cost savings in health care operations under the Affordable Care Act. For this reason, it is imperative that CMS and CMMI follow through on the Accountable Care Organization strategy and make it successful. A keystone to success is for the Administration to utilize a portion of the dollars appropriated by Congress to the Center for Medicare and

Medicaid Innovation and use them to provide healthcare providers with the infrastructure dollars needed to transform delivery systems. The money invested will allow the creation of delivery systems that support the Triple Aim of better care for individuals, better health for populations, and reduced per-capita costs for the Medicare program. Delivery systems transformed as ACOs, within a short time, will be able to accommodate population based payments from the government and private payers.

The need for the ability to invest in infrastructure to transition our delivery system from a fee for service design to a population health design was our overarching theme in our comments regarding the MSSP. We have estimated the cost to establish sustainable core competencies necessary to manage the care of defined populations at a price tag between 3 and 5 million dollars per affiliate region, depending on the size of the region. For our entire health system, we estimate a cost of 26 to 40 million dollars in infrastructure investment.

So, when we learned that CMS was considering a program by which the government would share in infrastructure cost, we thought CMS was right on target. After review of the program, we believe the opportunity offered to ACOs to apply for government funding to invest in infrastructure needs to be significantly modified. This issue is so important and fundamental that how CMS decides to go here will be the difference between the success and failure of the Medicare Shared Savings program. The bottom line is that if CMS makes infrastructure funds available as part of the MSSP, not as a loan program, but similar to a grant award, there will be a dramatic shift in the interest of the industry in participating in the MSSP.

Our suggestions in regard to design of infrastructure assistance for ACO development are:

(1) Infrastructure costs should be available for successful applicants of both the MSSP program and the Pioneer ACO program. Applicants of the Pioneer ACO program are taking on an even steeper challenge of transforming their entire payer base and committing to movement to a population based payment in year 3. Such facilities will have an even greater need to immediately invest in infrastructure than those that participate in the MSSP.

(2) The opportunity should be designed like a federal grant program rather than a loan program with recoupment provisions. A loan program with a recoupment provision is a non-starter for health care providers and denies the reality of the large infrastructure cost that health care providers will take on by participating in these programs. Both the shared savings dollars AND additional dollars through an award of infrastructure costs will be needed by healthcare providers to truly transform delivery systems.

(3) The application process for applying for infrastructure assistance should be wrapped into the application for the MSSP. Our suggestion is that when an applicant fills out the application to participate in the MSSP they indicate whether they will make a request for infrastructure dollars. If so, through the same application process, they would provide detailed information regarding the need for infrastructure assistance, an infrastructure budget, and detail on how award dollars will be spent.

(4) We suggest that applicants of the MSSP or the Pioneer ACO program be able to receive an award of infrastructure costs ranging from 3 to 8 percent of the benchmark spend for the assigned beneficiary population each year, paid as an upfront payment annually.

(5) Infrastructure costs should be available to both large integrated health systems as well as small physician practices who desire to become ACOs. Large health systems realize operating margins that are much less than small group physician practices. Further, CMS has the opportunity to get a lot of "bang for the buck" out of investing in large health systems. For example, we have estimated that our health system, if all affiliates operate at ACOs, will be accountable for approximately 300,000 Medicare lives.

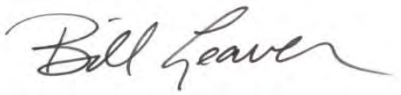
(6) Infrastructure costs should be available for the following categories: Care coordination; patient centeredness; IT; data gathering and data analytics; Reporting; Evaluation; ACO administration. Infrastructure rather than programmatic costs should be made available to ACOs.

(7) Once costs are awarded through the MSSP or the Pioneer ACO program, awardees should be accountable to the government for compliance with the budget set forth in the application. We envision compliance with guidelines similar to the federal grants process.

(8) Infrastructure investment is a 3 to 5 year process. Our belief is that much of the cost to transition health systems from fee for service to population based care entities will be one-time costs over a 3 to 5 year period. After that, our business model will be changed and further infrastructure assistance on behalf of the government will not be necessary.

We appreciate the opportunity to provide comments to the Advanced Payment program. We would be glad to discuss our comments and provide additional information on any of the topics addressed in these comments. We can be reached by contacting our VP of Government Relations, Sabra Rosener, at rosenesk@ihs.org

Sincerely,



Bill Leaver, President & CEO
Iowa Health System

IOWA HEALTH SYSTEM

June 16, 2011

VIA EMAIL

Donald M. Berwick, M.D., Administrator
Center for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS–1345–P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS–1345–P, Medicare Program: Medicare Shared Savings Program: Accountable Care Organizations – Advanced Payment Option

Dear Dr. Berwick:

Jefferson Health System, Inc. ("JHS") is a non-profit healthcare system serving the greater Philadelphia, Pennsylvania area. We appreciate the opportunity to comment on Center for Medicare & Medicaid Services' ("CMS") notice regarding the Medicare Shared Savings Program's Advanced Payment Option.

For the past nine months, JHS, in anticipation of participating in the Medicare Shared Savings Program, has been investigating forming a regional Accountable Care Organization ("ACO") that spans the Southeastern Pennsylvania region, one of the country's vital hubs for medical training, research and innovation in this country.

The ACO would develop, deploy and administer evidence-based protocols for acute care and chronic conditions, health information technology infrastructures, quality evaluation and management systems, and teams of care management professionals to meet the Shared Savings Program objectives of increasing the quality and efficiency of care while improving the patient experience.

An ACO in this market presents an unprecedented opportunity to materially improve the quality and efficiency of care and reduce per capita Medicare expenditures on a large scale by those who are in a unique position to do so – hospitals with the capital and organizational structures necessary to make these goals a reality.

At the same time, the ACO is presented with substantial challenges. Southeastern Pennsylvania remains a highly fragmented, specialty driven health care market serving an extremely diverse patient population. To date, providers in the market have had very limited, if

any, experience with payment models where they are at risk for clinical and financial performance on the scale contemplated by the Shared Savings Program.

Changing these market dynamics in a manner necessary to achieve the Shared Savings Program's goals will require massive investment and operational change that has taken providers in other service areas with smaller and more homogeneous populations ten years or more to achieve. This investment must occur very quickly without jeopardizing the participants' long term viability to fulfill their core mission of quality health care delivery. Time is of the essence as we face the immediate threat of crippling budget deficits and stand on the brink of the greatest expansion of the Medicare roles in history as the "baby boomers" become eligible to receive Medicare benefits. The regulatory environment must be one that encourages rather than discourages hospitals to make this investment and gives us the opportunity to quickly and markedly improve the quality and efficiency, and reduce the per capita cost of Medicare services in the fifth largest metropolitan area in the country.

JHS is mindful of and appreciates the fact that CMS has made a concerted effort to receive input and address the concerns of the numerous stakeholders in the proposed rule. At the same time, we remain deeply concerned that certain fundamental aspects of the rule as proposed create barriers to creating an ACO that can, in the near term, deliver the benefits that the Shared Savings Program has been created to achieve.

We continue to support the ACO concept, but, like others, we have serious concerns that the financial risks and burdens being imposed by the rule may be too great to permit a prudent organization to make the financial investment necessary to create and start up an ACO. JHS is pleased that CMS seems to have heard the concerns being voiced by potential participants in an ACO and is considering, and has asked for comment on, an Advanced Payment Program where ACOs would receive an advance on anticipated shared savings as a monthly payment for each aligned Medicare beneficiary.

JHS strongly supports the Advanced Payment concept. As set forth in our recently filed comments regarding the ACO regulations, creating and starting up an ACO under the proposed regulations requires a massive initial investment, offers a low likelihood of any positive return with a substantial possibility of losses above and beyond the initial investment. While the Advanced Payment option would clearly not alleviate all of the financial burdens and risks associated with the Shared Savings Program as proposed, the concept is a step in the right direction.

Our specific comments focus on two areas:

- Repayment of the Advanced Payment
- Timing of the Advance.

Repayment of Advanced Payment Should Only Come From Shared Savings Payments

While supporting the advanced payment concept, JHS is concerned about the details. If the program were to require the advance to be paid back regardless of whether the ACO was entitled to any shared savings payments, the advance would amount to merely a loan, and do little to ease the financial burden and risk to forming an ACO. Such a program would offer little incentive to participate in the Shared Savings Program. JHS recommends that the program require repayment of the advance only out of shared savings payments to which the ACO is entitled, if any.

If CMS were to insist on repayment regardless of whether savings were achieved, then the required repayment should be spread over a substantial period of time – at least ten years – and be in the form of reduced Fee-For-Service payments so as to lessen the financial impact on the ACO participants.

Advance Payment Should be a True Advance

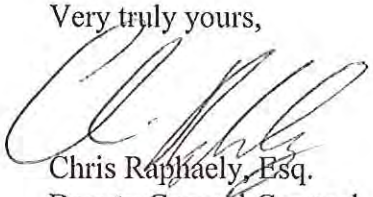
Although CMS has provided no details regarding the Advanced Payment Program, the notice did state that the advance payment would be in the form of a monthly payment for each aligned Medicare beneficiary.

Under the proposed Shared Savings Program rule, beneficiaries assigned to an ACO are determined retroactively, at the same time shared savings are calculated. If CMS were to use retroactively assigned beneficiaries as the basis for making the "advanced payments," such payments would not actually be advanced, but would be paid no sooner than any actual shared savings might be paid.

For any advanced payment program to provide a true incentive to participate in the Shared Savings Program, CMS must develop a methodology where the payments would actually be made in advance; not begin eighteen or more months after the start of operations.

Thank you for the opportunity to comment on the proposed Advanced Payment Option. If you have any questions about my comments or need further information, please contact me at 610-225-6217.

Very truly yours,



Chris Raphaely, Esq.
Deputy General Counsel

STATE OF MARYLAND

Marilyn Moon, Ph.D.
CHAIR

Ben Steffen
ACTING EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

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June 16, 2011

Richard J. Gilfillan, M.D.
Acting Director
Center for Medicare and Medicaid Innovation
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

RE: Advance Payment Initiative

Dear Dr. Gilfillan:

The Maryland Health Care Commission (MHCC) is pleased to offer the following comments on the Advance Payment Initiative for Accountable Care Organizations entering the Medicare Shared Savings program. Maryland's efforts to develop a similar methodology for its patient-centered medical home program may be relevant to CMS's work in this area.

The MHCC is an independent regulatory agency whose mission is to plan for health system needs, promote informed decision-making, increase accountability, and improve access in a rapidly changing health care environment by providing timely and accurate information on availability, cost, and quality of services to policy makers, purchasers, providers and the public. The Commission's vision for Maryland is to ensure that informed consumers hold the health care system accountable and have access to affordable and appropriate health care services through programs that serve as models for the nation.

The CMS Innovation Center has requested comment on an Advance Payment Initiative for those ACOs entering the Medicare Shared Savings Program. CMS has stated, "Some providers have expressed a concern about their lack of ready access to the capital needed to invest in infrastructure and staff for care coordination. Under the proposed initiative, eligible organizations could receive an advance on the shared savings they are expected to earn as a monthly payment for each aligned Medicare beneficiary. ACOs would need to provide a plan for using these funds to build

care coordination capabilities, and meet other organizational criteria. Advance payments would be recouped through the ACOs' earned shared savings." This model is very similar to the methodology for PCMH payment we are implementing in Maryland, and our experience may provide helpful guidance.

Since April 2010, the MHCC has been working to design and implement a patient-centered medical home (PCMH) program. Program participants include five commercial health insurance plans, the state Medicaid program, the state and federal employees benefit plans, and 54 primary care practices serving approximately 300,000 patients. The concept of shared savings is central to the financial model for the Maryland PCMH program, since any model that requires health care purchasers to contribute "new money" to PCMH payment would not be sustainable. Using analysis conducted by Prometheus Payment and Discern Consulting, we have estimated the savings that could be generated by PCMH practices through avoidance of unnecessary hospital admissions, emergency room visits, and other health care complications. For commercial insurance populations, we have estimated this savings potential to be $283 per patient per year; for Medicare populations, we believe the savings potential is closer to $700 per patient per year.

Savings of the magnitude cited above are only attainable after primary care practices transform themselves into PCMHs. That requires time and money, both of which are scarce resources for many health care providers, especially primary care practices. We therefore adopted a methodology for payment to the PCMH practices to help them invest in the changes necessary to operate as a PCMH. This "fixed transformation payment" (FTP) is made on a per patient basis, and is calculated as 25% of the projected savings from the PCMH. For a typical primary care practice, the FTP is about $60 per patient per year for a commercially-insured patient. The FTP actually ranges between $42 and $72 per year, and is adjusted based on NCQA compliance level and the size of the PCMH. Smaller primary care practices receive a higher per patient FTP, because they must spread the fixed costs of PCMH operations over a smaller population.

In the Maryland program, the FTPs are treated as "pre-payments" for projected savings. PCMHs will need to generate savings that exceed the FTP payments they have already received before they are eligible for any payments under the shared savings methodology. As we understand it, this is very similar to the Advance Payment Initiative proposed by CMS. However, pre-payments raise a concern: the health purchaser is asked to make an upfront payment for a future, uncertain benefit. If the PCMH fails to generate savings at least equal to the pre-payment, the purchaser will lose money. As such, pre-payments represent a shift of risk from the provider to the purchaser.

Financial tools are available that can help to reconcile issues related to immediate investments made in anticipation of future, uncertain returns. Specifically, we can use the concept of Net Present Value to translate the expected future savings from the medical home into present-day payments that account for the time needed to achieve savings and the riskiness inherent in generating savings. By choosing an appropriate time horizon and discount rate, we can convert the expected future savings into a present value1, which can then be used as the basis for the pre-payment.

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[1] We calculate Present Value (PV) by using the equation $PV = FV \div ((1+D)^T)$, where:
FV = Future Value (i.e., the savings we expect to accrue from the PCMH)
D = Annual Discount Rate
T = Time (in years) until the Future Value is generated

In Maryland, we have used a time horizon of one year. We feel this is consistent with the evidence that, once a primary care practice completes the PCMH transformation process, the benefits to patients occur soon thereafter. For example, once a primary care practice implements 24/7 access to medical consultation, there should be an immediate reduction in inappropriate emergency room utilization. We have selected a discount rate of 6%, which is fairly low and close to a "risk-free" rate. Using a low rate accounts for the time value of money; health purchasers make the FTP payments now and do not accrue the value until a year later. That time lag between payment and return is reflected in the Present Value calculation using a low discount rate. Using a low discount rate is a policy decision we made at the MHCC. We wanted to acknowledge the time value of the FTPs made to primary care practices, but we concluded it that the purchasers should bear some of the risk of whether savings would be achieved. A higher discount rate could be used to reflect the inherent riskiness and uncertainty about whether savings will be achieved at all, and would reduce the risk for the purchasers while increasing it for the providers.

Choosing an appropriate time horizon and discount rate for the Advance Payment Initiative would be an imprecise process, because there are many unknowns regarding how, and how quickly, ACOs will generate savings. But using Present Value as a method to calculate the Advance Payments would provide a framework to ask all the pertinent questions about the ACO savings mechanism, and then aggregating the answers to those questions into a meaning result. The key questions are:

- How much savings do we expect an ACO to generate?
- What is the time horizon for generating savings in an ACO?
- How certain are we that savings will actually be achieved?

The answers to these questions can be used to do a Present Value calculation, which could provide useful guidance on the structure and amounts of the Advance Payments in the ACO shared savings program.

Thank you for the opportunity to comment on the Advance Payment Initiative. We would welcome the opportunity to share more information about our PCMH efforts here in Maryland, and how they relate to your work. Please feel free to contact me at 410-764-3573 or bsteffen@mhcc.state.md.us.

Sincerely,

Ben Steffen
Acting Executive Director

MSNJ
MEDICAL SOCIETY
OF NEW JERSEY

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June 17, 2011

Dr. Mandy Cohen
Director of Stakeholder Engagement
CMS Innovation Center
advpayaco@cms.hhs.gov

Re: Advanced Payment Initiative of the CMS Innovation Center

Dear Dr. Cohen:

The Medical Society of New Jersey (MSNJ) appreciates this opportunity to provide comments on the Innovation Center's request for information on how it might design an advanced payment element to increase participation in the Medicare Shared Savings Program. MSNJ is a non-profit physician member organization with approximately 8,000 members. We are the largest physician organization in the state. Most of our members are in a solo or small practice.

MSNJ strongly supports the concept of advanced payment as a means to enable more physicians, especially those in small practices, to participate in accountable care organizations (ACOs). In fact, we believe that an advanced payment concept is essential for many physicians to be able to participate in an ACO as their access to capital is limited. We urge the Innovation Center to adopt more than one advance payment model and to make participation as flexible as possible. At the same time, we urge simplicity rather than more complexity as the ACO rule is already complex and will require significant capital and human resources to implement.

We ask that you consider the following suggestions:

- Develop More than One Advance Payment Model;
- Develop an Optional "Early Decision" Track; and
- Forbear on Recoupment Under Certain Circumstances.

Develop More than One Advance Payment Model

More than one model for advance payment is necessary to address the different capital needs of potential ACO participants.

MSNJ believes that start-up costs have been sorely underestimated and many new entrants to ACOs will simply not be able to participate. There are a number of examples of start-up costs that present barriers. For potential ACO participants that are lacking essential infrastructure, risk analysis skills, clinical and care coordination capability, an advance payment on the front end is necessary. This is particularly true for ACOs that lack information technology. In these situations we suggest that an up-front, lump sum, payment be made. The payment amount should be targeted to defray the identified need, but not more than would reasonably be expected to be achieved in savings.

Some potential ACO participants will have necessary infrastructure and be better able to absorb start-up costs, but not be adequately capitalized to implement care coordination. In these situations, potential ACO participants may wish to receive per/ member per/month advance payment to absorb administration and management costs. Advance payment design should allow for such per/member per/month payments. Whether these funds are needed up-front, or on a monthly basis, is best judged by the potential ACO. The Innovation Center should consider advance payment in a lump-sum amount based on a per/member per/month analysis or paid monthly.

Develop an Optional Early Decision Track

Since access to start-up costs may be crucial as to whether an ACO will go forward, we suggest that there be an optional early decision track for potential ACOs. This would allow ACOs who do not receive an early commitment on advance payment to consider other sources of capital or abandon their pursuit of an ACO. An applicant for an early decision on advance payment would have to demonstrate how they would use either up-front funds or monthly payments to achieve the goals of ACOs. With a commitment to an advance payment, the ACO would still have to file a successful application, but it may not be necessary to complete certain parts of the application that would be deemed complete or to have been satisfied through the successful advance payment process.

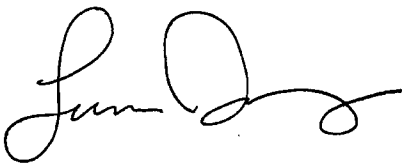
Forbear on Recoupment in Certain Circumstances

Even with access to advance payment potential ACOs are assuming financial risk under the current ACO rule proposal. The premise of an advance payment on savings assumes that there will be savings beyond the 2% threshold necessary for ACOs to achieve any savings. MSNJ urges the Innovation Center to consult with CMS and consider whether there are circumstances where the Federal Government would forbear on recouping against the shared savings.

We are concerned that it may not be possible to accurately predict when savings will be achieved. Moreover, it is possible that savings will be achieved, but not within the three-year time frame. Recouping against advance payments could be devastating to an ACO that is providing higher quality care and contributing to better health, but may not yet have reached the calculated savings within three years. We urge that consideration be given to an extension of the three-year time frame during which no recoupment would be

made so long as quality goals were being achieved and the cost of care was not exceeding the regional cost average.

Respectfully submitted,



Lawrence Downs, Esq.
General Counsel
Medical Society of New Jersey

I would suggest that CMMI require Advanced Payment ACO's to submit an outline/plan for use of upfront shared savings payments.

From my notes of the call, IT costs were a key component of these anticipated expenses and I would propose an IT solution.

I have submitted two suggestions to CMMI focused on the acceleration of innovation resulting from networking employee suggestion systems (ESS) embedded in ACO's. Accountable Care Organizations which do not network these silos of frontline innovation will innovate at a 70% to 140% slower rate than ACO's embracing this networking tool, which is merely a link on the ACO homepage. Utilizing this tool would enable financially disadvantaged ACO's to reach shared savings thresholds much sooner.

Thanks for the opportunity to participate in the call.

Timothy Myers

National Association of Public Hospitals and Health Systems

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June 17, 2011

Richard Gilfillan, M.D.
Acting Director
Center for Medicare and Medicaid Innovation
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Ref: Medicare Shared Savings Program - Advanced Payment Initiative

Dear Dr. Gilfillan:

The National Association of Public Hospitals and Health Systems (NAPH) appreciates the opportunity to submit comments on the above captioned proposal. NAPH represents the nation's largest metropolitan area safety net hospitals and health systems, many of which have integrated care delivery systems. Our members are well positioned to adopt health reform delivery models by implementing coordinated care strategies for our vulnerable populations. Although our members treat a larger portion of Medicaid beneficiaries than Medicare beneficiaries, they also see a disproportionate share of dual-eligibles, a population with unique challenges and that accounts for 36 percent of Medicare expenditures and 39 percent of Medicaid expenditures. Given our long experience in treating the nation's poorest and most vulnerable patients, including dual-eligibles, we strongly encourage the Center for Medicare and Medicaid Innovation (CMMI) to consider our proposed Safety Net Accountable Care Organization (ACO) Demonstration, which is designed to test effective models of care for low-income patients.

In concert with the Centers for Medicare & Medicaid Services' implementation of the Medicare Shared Savings Program (MSSP), the CMMI is considering launching a companion initiative for those ACOs entering the MSSP that would pre-pay a portion of future shared savings in an effort to increase participation in the MSSP. NAPH strongly agrees with the CMMI that certain providers need additional support in order to participate in ACOs. Safety net health systems simply do not have the disposable resources to make the investments that are required by the MSSP as proposed, including investments in technology, process redesign, personnel, care coordination, quality measurement, risk management, compliance, network development, governance and legal structure. Moreover, the potential for shared savings is not nearly significant enough or sufficiently attainable to warrant such investments even if the disposable funding were available. Therefore, to the extent that CMS desires the participation of these providers and the patients they serve in the MSSP, NAPH recommends that the CMS and/or CMMI provide funding to help cover these significant investment costs, and improve the

potential for shared savings for safety net providers. Such support should also be part of any Safety Net ACO Demonstration.

NAPH recommends that the CMMI implement this companion initiative in a way that encourages broad participation by safety net health systems that treat a disproportionate share of low-income patients with complex needs. While advanced payment of shared savings that would otherwise be due at the end of a performance year may be an appropriate incentive for some providers to participate, it is not enough for true safety net providers with their often narrow or negative margins. NAPH strongly urges the CMMI to provide upfront resources to these safety net health systems as grants prior to the start of the ACO agreement period. Because the Medicare populations served by NAPH member systems are disproportionately comprised of low-income, dual-eligible patients, and the challenges of serving and effectively coordinating the care of this population are substantially higher than for the average Medicare patient, these typically under-resourced providers need the extra help. Unlike most hospitals, they do not have a substantial commercial patient base from which they can expect to reap additional rewards from their investments in care coordination. In addition, most, if not all, of the shared savings they earn will need to be reinvested into the ACO to support ongoing (as opposed to start-up) resource-intensive coordination and case management efforts. Without these upfront grants, the substantial investments required for participation in the MSSP will discourage participation of these safety net providers in the program or others like them.

NAPH encourages the CMMI to concentrate these resources on providers carrying the largest burden of low-income care—demonstrated by a low-income utilization rate (as defined in section 1923(b)(3) of the Social Security Act) of at least 25 percent—and/or a significant uncompensated care burden—as determined by the ratio of a hospital's uncompensated costs (i.e. its hospital-specific disproportionate share hospital (DSH) cap specified in Section 1923(g)) to total operating expenses. Both of these metrics are widely-accepted, long-standing metrics that can help determine whether the participating provider treats a substantial share of uninsured, Medicaid, and other vulnerable patients. Specifically, the low-income utilization rate incorporates Medicaid and charity care volumes and the hospital-specific DSH cap incorporates uncompensated cost of services provided to Medicaid and uninsured patients. In addition, the Institute of Medicine also uses the substantial share criteria to distinguish core safety net providers from non-core providers. NAPH encourages the CMMI to use these metrics as a guide when determining an ACO participant's commitment to its safety net mission and financial need.

Lastly, we reiterate our recommendation that the CMMI establish a Safety Net ACO learning collaborative that would support safety net ACOs participating in the MSSP or other CMS-sponsored ACO programs and demonstrations. Technical assistance and peer learning will be essential for all ACOs, but particularly for those serving safety net populations. CMS could significantly boost the ability of these providers to participate in innovative new delivery models by providing focused resources to support their efforts. NAPH, through its newly-established Transformation Center, stands ready to partner with the CMMI in this endeavor.

* * * * * * *

NAPH appreciates the opportunity to submit these comments. We strongly support reform of the health care delivery system through greater collaboration as envisioned in the ACO model. Toward this end, we again strongly urge the CMMI to consider our proposed Safety Net ACO Demonstration to help improve care delivery for the special vulnerable populations served by our nation's safety net. If you have any questions, please contact Xiaoyi Huang at (202) 585-0127.

Sincerely,

Bruce Siegel, MD, MPH
Chief Executive Officer

The Innovation Center wants your feedback on how an Advance Payment Initiative should be designed.

Our company, OTI America, has developed and deployed Medicaid applications with hundreds of thousands of benefit recipients using our solutions today. The original purpose of this application was to eliminate fraud and abuse, identify and authenticate recipients, manage claims, up to date benefit eligibility at every encounter, maintain a portable record, to name a few of the apps. One of the apps is an Advanced Payment. We have developed benefit pools or buckets where the benefits are stored for things such as Hospital In-Out encounters, clinic encounters, labs, pharmacy, dental etc.. At the point of service the provider can be paid out of the appropriate pool or bucket of funds. Real time information is provided back to the benefit provider regarding payments, eligibility and encounter coding and more.

If you'd like to know more about this application please contact me at your convenience.

Best regards,

John Rego

Director of Sales - Emerging Markets & Technologies
OTI America

I'm concerned about the following statement copied from the healtchcare.gov web site please see my comment below:

ACOs would need to provide a plan for using these funds to build care coordination capabilities, and meet other organizational criteria. Advance payments would be recouped through the ACOs' earned shared savings.

There needs to be something in place for those organizations who do not realize savings. Advanced payments, if not recouped through earned savings over a defined period of time, need to be treated as a loan and paid back to the government. If providers or organizations are not serious and held accountable for their actions like any other business then there needs to be safeguards so this program does not turn into a free stream of cash with no results and only pushing healthcare costs higher.

Thanks for listening and if you are looking to hire anyone with 30+ years of healthcare and health insurance experience in the Boston area, let me know.

James F. Powell

To whom it may concern:

I realize this communication is late, but your email announcement was just forwarded to me today.

I have extensive experience with provider advance payments methodologies. My first company, Information Network Corporation ("INC") was an early on (1982) technology sub-contractor to health plans participating with the Arizona Health Care Cost Containment System ("AHCCCS"). INC provided integrated system modules encompassing all plan administrative and regulatory reporting functions necessary for Medicaid health plans to achieve success. At the peak of the company's production INC's AHCCCS health plan customers collectively served more than 50% of the programs recipients and hundreds of thousands of recipient lives serviced by Medicaid Managed Care plans in 10 other states.

The sustained growth of INC was, in no minor way, due to a unique claims administration feature … the ability for plans to advance funds to providers and offset future claims against those advances post adjudication. When plans compared INC to the competition, The INC System was found to be the "provider friendly" option for them. Provider friendly meant that plans could advance sums to providers for virtually any reason or purpose they felt appropriate or strategic. Advance balances could be posted at the either the provider level (a bulk advance with no specific claim reference) or claim-specific.

Necessity being the mother of invention, this is how it came about. The Innovation Center can determine if either of the two following "necessities" applies, directly or indirectly, to what you wish to accomplish with the Shared Savings Program.

A request received by INC for a provider advancing methodology came from an AHCCCS plan known as Patient's Choice. The plan had been purchased by Peak Health Plan of Colorado Springs which at the time was a newly acquired unit of United Health Care. Peak's CEO at the time was Dr. Bill Maguire and we all know how that worked out for him. But I digress. Upon acquisition, Peak found that provider reimbursements were so far behind that mass mutiny was what Peak faced upon taking control. They laid much of the blame with the then systems vendor and was referred to INC as a potential systems alternative by AHCCCS.

Peak outlined their problem with the providers and asked how quickly we could process the backlog of un-adjudicated claims. The volume was beyond imagination and there was a zero possibility that INC could make a substantive dent in the claims payable in a time frame that would alleviate the pending problem of Peak's newly purchase provider network disintegrating.

After considering the predicament that Peak was in INC came up with the following action plan:

1. Peak representatives would make personal calls on each non-facility provider. The representatives would ask each provider to provide them with reports from their internal accounts receivable system itemizing Peak's outstanding claims.

2. Peak would then write a check, on the spot, for 50% of the providers Peak receivable.

3. INC would then post the bulk payment (with appropriate audit trail) to an "Advance Balance" to be created in the Provider Data Base.

4. Peak would also inform the providers that beginning with the first day of the following month that a "special advance payment remittance advice" with a 50% payment of billed charges would be created with payment remitted within 7 days of receipt.

5. INC would post those advances to the pending claim transaction and to the Advance Balance in the Provider Data Base.

This process was to continue until Peak's claims payable were routinely in a 30 day awaiting payment lag period for clean claims … which was accomplished.

During the adjudication process for claims with specific advances, the adjudicated payable amounts were reduced by the amount of that claim's advance creating a "net" payable. The Advance Balance in the Provider Data Base was reduced by an amount equal to the claim's advance amount as well. If the claim advance exceeded the adjudicated payable the Advance Balance would be reduced by the adjudicated claim liability amount leaving the difference in the Advance Balance because those claims had been "over advanced".

The Advance Balance also included those "on the spot" bulk checks written without regard to specific claims. The back-log of claims that were not "auto-advanced" upon receipt and all future claims received after the auto-advancing was discontinued were applied first to the Advance Balance until it reached zero. Thereafter, claims were paid routinely.

Sorry for so much detail here, but by providing it I'm sure that you will see the value of the process. Another AHCCCS plan participating with the long term care program used the bulk payment feature to advance SNFs. Other plans in other states used the bulk advance feature to secure favorable terms with particular specialty providers where they had holes in their networks, etc. One or two other plans used the auto-advance feature as a standard operating procedure.

I have offered the scenarios above as a successful approach to claim advancing. However, I do not have enough information on the Shared Savings program to know how that might fit or what modifications to the process may be necessary to accomplish what CMS envisions.

I am still involved with assisting providers with the lack of timeliness in their revenue cycles. I sold INC to the Medicaid/Medicare business unit of United Health Care in 1998 staying on until 2002. Following a long non-compete period I recently founded Provider Funding Services, LLC. I will now begin to work directly with providers and their lenders to stabilize their cash flows. It involves advances from a revolving credit line … not advances from payer organizations.

I became very much aware of how dependent small providers are with the timeliness of reimbursement way back in the Peak days. That situation was obviously different than what providers have recently faced with the payer systems changes to accommodate the NPI conversion and what they will face due to the impact that ICD-10 will have on both payer and provider systems.

It is interesting, at least to me, how applying creative thought to Peak's problem has led to a new business model 30 years later. Who knows, perhaps the answer to an advancing process for improving the adoption rate of the Shared Savings program lies in some combination of CMS' claims processing applications and external bank financing. To read more about how I go about the provider advancing

business these days, please see my website at the link below. I wish you success in finding a method for improving the operating cash flows for providers that participate in the Shared Savings program.

Respectfully,

R.J. Voth, Sr.
Provider Funding Services, LLC

~~**Raymond Basri, MD, FACP**~~
~~236 Crystal Run Rd, Ste. 2~~
~~Middletown, NY 10941~~
~~(845) 692 - 3100~~

~~**Subject:**~~ Accountable Care Organizations (ACOs) and Small Practices

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My physician colleagues in primary care should give serious thought before

~~I sincerely enjoyed the presentation and discussion related to the proposed Accountable Care Organizations (ACOs) at the Rochester meeting. The purpose of this memo is to advocate against internists~~ participating ~~based~~ in ACOs. They may find their economic well-being threatened from a new government imposed program~~ity~~. There are several key issues:

- Partnership between primary care physicians and hospitals are inherently unbalanced
- High cost of forming structure and hiring consultants
- Hospitals can coerce primary care participation
- Poor transparency due to delays in collecting data and reporting

I believe that there are a number of inherent issues related to the structure of ACOs.

1. ACO's will concentrate power in the hands of hospital administrators, large multispecialty groups, and hospital-based physicians to the detriment of office based primary care physicians. We should look at ACO's as an effort to extend the economic reach of those entities into the individual medical offices that provide the overwhelming volume of medical care to the community.
2. Partnerships between physicians and hospitals are inherently unbalanced. Physicians are predominantly in small groups or single practice. They lack the financial means to hire the lawyers, accountants, and consultants to negotiate favorable terms to structure a new ACO.
3. Primary care physicians are the potential gatekeepers to patient access to high cost specialists and hospital services. The economic significance of primary care physicians as decision-makers may not be adequately compensated within this structure.
4. ACO's will replace the health-insurance payers we currently have and transform~~place~~ themselves as all-powerful fiscal intermediaries. This means that all revenue coming to our practices will be subject to an ACO's discretion. Obviously, when times get tough they will take the first dollar for their administration and overhead rather than pay us.
5. ACOs may assert a geographic sphere of authority to control an individual physician or practice. Some physicians may need to choose to join one, but not both ACO's covering their existing hospital affiliations.
6. ACO's may try to secure their economic viability by inserting language into their contracts with private payers and HMOs that exclude continued contracting with medical practices that are not part of the ACO.

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7. Hospitals will use economic credentialing to deny privileges to physicians that do not join their ACO. They may contend that any physician that does not join the ACO will not be fulfilling their obligation to financially support the hospital. ACO's may use hospital administrators to run their operations and expect primary care physicians to be consistent referral sources for all their services.
~~1.~~8. The startup cost for an ACO is high. Delayed payments to hospitals and large medical groups with lines of credit may adversely impact small primary care practices disproportionately.
~~1.~~9. The hospitals are often top-heavy with administrators and overhead. They maintain high~~-~~cost, revenue~~-~~negative services that primary care physicians will be asked to support through referrals and ultimately sharing in those fixed costs.
~~1.~~10. Hospitals will not offer financial transparency to physicians concerning their own complex financial structure which may hide unprofitable services. Furthermore, many hospitals have multiple "philanthropic" corporations that they use to hide costs. We do not have the accountants to ferret out waste.
~~1.~~11. Hospitals will view medical service providers that compete with them as unnecessary competition. Hospitals may deny access to primary care physicians that they deem as disloyal. This is more likely if a primary care physician maintains admitting privileges to more than one hospital. Successful diagnostic radiology or physical therapy practices in the community may be targeted.
~~1.~~12. Hospitals are likely to favor surgeons and hospital-based specialists in any revenue negotiations so that they support hospital-based services. They need to maintain their revenue despite the obvious contradiction in lower utilization benefiting the ACO.
~~1.~~13. Small revenue adjustments made by the ACO will be unfairly burdensome on office~~-~~ based primary care physicians. An ACO may view minor revenue reductions as cost sharing across all its members and to be equitable for all parties. On a percentage basis, this may seem reasonable, but to small medical practices, ~~such as the internists we represent~~ this has the potential for devastating economic impact. We cannot cut our overhead for unilaterally imposed reductions in our revenue.
~~1.~~14. ACOs may advocate that payers not contract with any medical practices that do not participate with them directly. They will not take the risk that independent practices will refer patients to an ACO where they are not members.
~~1.~~15. Individual physicians may be placed into ACO's without their express permission by language and existing contracts to IPAs or payers that allow their services to be brokered by third parties.
~~1.~~16. ACO~~'~~s will need to compile financial data and display it in a transparent manner. Delays in compiling data will place an increasing financial burden on small medical practices dependent upon timely payment.
~~1.~~17. Physicians in small medical practices will be unduly pressured to adopt EMR systems that may be overpriced or poorly designed for their individual needs. ACO~~'~~s may contract with a preferred EMR vendor and coerce participation.
~~1.~~18. ~~Our members~~ Physicians may find that their current claims adjudication software or outsourced practice management company is not acceptable to the ACO. In terms of maintaining a revenue to sustain their medical practices, a potential disruption in the cash flow may be devastating.

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~~The NYACP~~ MSSNY should advocate for resolutions that support ~~internist's~~physicians' autonomy concerning ACO's without retribution for refusal to participate. This strategy should allow our members to weigh all the issues of participation fairly.

~~Thank you for allowing me to comment on this issue.~~

~~Respectfully submitted,~~

~~Ray Basri, MD, FACP~~

Raymond Basri, MD, FACP
Middletown, NY 10941

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We support the notion of Advanced Payment Initiative for smaller providers, such as primary care organization, who are not well capitalized like hospital or health systems. We have a proven track record, reviewed by third parties, that show that Primary Care Organizations can improve quality and decrease costs while operating more efficiently than hospitals or health system based organizations. Whether for us or other organizations, these advance payments would fund administration (inclusive of nurses for clinical outreach) and technology solutions to ensure that we have real time reporting mechanism to managed the quality, outcomes, and economic measures necessary to perform well under an ACO model. Additionally, advance payment would assist in the obtainment of Letter of Credits or reinsurance necessary to fund shortfalls.

Thank you for the opportunity to provide input. Please do not hesitate to contact me if there are questions.

Best regards,

Po Chou
Chief Operating Officer
Renaissance Medical Management Company

It is unclear to me how the ACO/Medicare system will provide post acute rehab services.

Also, the capitation systems that make the healthcare provider one as the insurance company has an inherent conflict of interest. This will likely create a patient dissatisfaction as they believe providers don't allow needed treatments to save money. This will also increase the tort filings, since financial motivation will be something the lawyers will use against the providers.

Richard H Salter

Richard H Salter

Summit Medical Group, PLLC

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June 17, 2011

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1345-P
P. O. Box 8013
Baltimore, MD 21244-8013

Medicare ACO Payment of Savings – Interim Payments and Final Settlement

We are very pleased that CMS has heard the industry concerns regarding the financial barriers to MSSP/ACO adoption. We have undertaken careful study of the issues, concerns and reasonably possible scenarios for credible and sophisticated ACO efforts. Interim payments will likely stimulate interest in the MSSP and Medicare ACO formation, as well as, allow the ACO to invest yet more resources into the program and thereby reduce the risk of losses, improve quality yet further and bring greater success to everyone's efforts.

We understand the Medicare ACO effort requires considerable effort, expense and performance before the determination of savings can be made. Further, seasonality of cost shares, weather impinged access to care, as well as, seasonal health conditions can provide variability relative to the full year performance.

To strike a balance between the burden of program operations and protection of the taxpayer we propose the following structure:

<u>Interim Payment for Favorable Results</u>

1. Quarterly payments, two quarters in arrears. For example: payment for the 1st qtr of a performance year would be paid at the end of the 3rd qtr.
    a. This allows five months of claims run out.
    b. Reduces the level of IBNR estimate to less than 5% of the total claims cost
    c. Minimum Savings Rate equates to a 40% error in the IBNR estimate – extremely unlikely. MSR also protects against seasonal fluctuations.

2. Payment level is 80% of otherwise payable amount, 20% withheld pending final performance year and subsequent quarterly calculations.
    a. Withhold provides protection from seasonal expense fluctuations.
    b. Provides additional safety margin for IBNR errors.

3. Each Quarterly Payment is calculated on a performance year to date bases.
    a. Maintains a 20% withhold.
    b. Adjusts for seasonality on a current basis.
    c. Minimizes swings in cash flow.
    d. Minimizes variability and exposure to large changes in position for full year calculations.
4. The interceding quarters between the payment quarter and the calculation quarter are evaluated. If there is an anticipated deficit, this deficit will be deducted from any otherwise payable amount. Such deficit is limited to the Track in which the ACO is contracted in for the payment quarter.
    a. Performance year calculations must stay internal to the performance year otherwise "upside only" payments could be used to offset downside experience in follow on contract years. This effectively puts the ACO at downside risk during an upside only time period.
    b. Track 2 financial structures – downside risk protection – should be completely internal to that performance year, to do otherwise overly complicates and may expose taxpayer to undue risk. There is no guarantee that a Track 1 ACO will convert, renew a contract to a Track 2 contractor.

Final Performance Year Payment

1. The final payment for a performance year shall be made in the third quarter following the close of the performance year and will be calculated for the performance year in totality.
    a. Any available withholds will be paid at this time.
    b. Payment is not subject to follow on performance year calculations

Recapture of over payments or down side risk (Track 2) payments to CMS.

1. In the event a payment calculation for a quarter (including interceding quarters) or the annual performance year in totality results in either a lesser payment amount up to and including a no payment amount (or payable amount to CMS in the case of a Track 2 ACO) the ACO shall have the following options of repayment
    a. Offset against the following year performance payments, if the interceding quarters otherwise indicate a surplus, or
    b. Equal quarterly repayment to CMS of any amount outstanding after an offset in paragraph a.

2. In no event is the ACO obligated to make payments for current performance year deficits or recaptures until the calculation of the performance year in its entirety.
    a. Keeps the ACOs engaged in the care coordination and quality improvement in the event of highly seasonal results.
    b. CMS is likely to stay in a net saving position through this scenario in the event of Track 1 quarterly overpayment.
        i. CMS has retained the 2% MSR
        ii. CMS has retained 20% of the payment.
            1. ACO would have to swing to a loss.
            2. The loss level is MSR rate + 20% of the previous savings level

3. Example: 5% savings level in Q1 would result in a payment of 80% of 3% i.e. 2.4%. CMS holds 2.6% of Q1 Benchmark.
4. Losses for the full year would have to exceed MSR
5. .15% of the full year benchmark to require the ACO to repay CMS.

Again, we appreciate the opportunity to share our perspectives on this important topic.

As always, if you have any questions please do not hesitate to call me.

Sincerely,

Tim Young, MPH, CMPE, MT
Chief Executive Officer

June 16, 2011

Richard J. Gilfillan**,** M.D**.,** is Acting Director
Centers for Medicare and Medicaid Services (CMS)
Center for Medicare and Medicaid Innovation (CMMI)
7500 Security Blvd.
Baltimore, MD 21244

Re: **Advance Payment Initiative for ACO's entering the Medicare Shared Savings Program (Sec 3022 of the Affordable Care Act)**

Dear Acting Director Gilfillan:

The American College of Physicians (ACP), consisting of 130,000 internal medicine physician specialists and student members, appreciates this opportunity to comment on the *Advance Payment Initiative for ACO's entering the Medicare Shared Savings Program.* Although details of this initiative are only broadly stated, it is our understanding that the CMMI is proposing to test whether the pre-paying of a portion of future shared savings would increase participation in the Medicare Shared Savings/Accountable Care Program. These advanced payments would be used by participants in the program to build care coordination capabilities, and meet other organizational criteria. It is also our understanding that entities receiving these funds that are not able to achieve savings equivalent to the advanced payment, would be responsible to repay CMS any difference.

ACP strongly supports the Advanced Payment Initiative and commends the CMMI for its release and development. We believe that a major barrier for participation within the Shared Savings Program, particularly for collaborations among primary care physicians and multi-specialty groups dominated by primary care physicians, is the availability of the up-front capital required to develop the organizational structure, health information technology (HIT) and integrative infrastructure, and service delivery capabilities (e.g. increased access, care management) that are necessary to succeed under this payment model. The availability of capital through this program, if implemented in a reasonable manner, should help address this barrier and increase participation.

The College, in addition to our general support of the concept of the Advanced Payment Initiative, offers the following recommendations and issues to consider in further developing this initiative:

- **The College recommends that applicants for this initiative have the option to receive the advanced payments upfront, or through a hybrid payment model in which a significant portion is received upfront and the remainder provided as a periodic payment.** This is based on feedback from our membership, exemplifying both potential collaborations among small practices and larger entities already organized in an integrative structure, recognizing the

need for early access to capital to develop the above described capabilities to succeed under the Shared Savings payment model. In considering applicants for advanced payments, the College further suggests that:

- **Participation within this upfront payment option be limited to those entities that, through the information provided in their application, are projected to have a high likelihood of succeeding under this model.** The College believes that the Shared Savings/ACO model has the potential to improve physician payment and align it with such important factors as improved quality, efficiency, care integration, and patient-centeredness. Thus limiting, at this early stage, participation in this option of the initiative to those most likely to succeed would be prudent and more likely to support the model's further expansion. Factors to consider could include:
  - A detailed plan to develop (with an associated timeline) or actual progress toward the development of the necessary organizational structure, health information and integrative infrastructure, and service delivery capabilities required for successful participation within the Shared Savings Program.
  - A detailed plan to develop or actual progress toward the establishment of collaborative relationships (including contracts) with providers within the "medical neighborhood" that are not directly participating partners within the ACO.
  - A detailed plan to establish or the actual establishment of contracts with other payers.
  - A detailed plan to transform or actual progress toward the successful transformation of participating primary care practices into recognized Patient Centered Medical Homes (PCMH).
  - A detailed and documented process to payback CMS if achieved savings are less than the advanced amount. Entities should be provided with a reasonable payback period (e.g. at least three years from receipt of the advanced payment).
  - A documented history of successful integrative collaboration.

- **The CMMI should also consider developing a second option where payments are released incrementally based upon the participating entity achieving developmental goals reflected in their application.** This approach would be particularly beneficial for those entities that are in the early stages of ACO development. Such an approach would lessen the risk to both CMS and the ACO entity regarding the accruing of significant loses. These goals could include the establishment of an integrative administrative structure, the signing of a contract to provide necessary HIT infrastructure among the ACO's participants, the accomplishment of a viable integrative infrastructure among the participants, documenting the ability to collect necessary performance data, achieving a certain percentage of PCMH recognition among their participating primary care practices, and establishing various service delivery capabilities.

- **The CMMI should set-aside a portion of funds available for this Advanced Payment Initiative specifically for efforts by small and medium size, independent primary care practices to enter into formal collaboration and participate within the Shared Savings Program.** The College makes this recommendation for two primary reasons: 1) These are the type of practices that still provide the majority of clinical care to our Medicare beneficiaries, and 2) these are the type of collaborations most in need of upfront capital to develop the capabilities to participate successfully. Access to these partitioned funds should be on a competitive basis and limited to those entities estimated to have the highest likelihood of success. **In addition to access to advanced capital, the ability to provide these entities with sources of technical support and guidance would be an important component to help ensure success.** We are suggesting something more than the Accelerated Developmental Learning Sessions currently being offered by the CMMI. The support could take the form of the type of assistance currently being provided under the Regional Extension Programs established through the HITECH legislation or authorized under the Affordable Care Act legislation; through expanding the scope of work of the Quality Improvement Organizations (QIOs); or through partnerships with other local, regional, and national entities. These assistance programs can also help these smaller practices prepare (engage in necessary practice transformation) for successful integration into already existing ACO entities or integrated systems, if they choose to do so.

The College acknowledges that the new Shared Savings/ACO option is just one of many approaches (e.g. PCMH, Risk Adjusted Comprehensive Payment, partial and total capitation, Prometheus Episode Payment) that may potentially be available to our members and can provide savings and improve care delivery to our beneficiaries. The Advanced Payment Initiative facilitates entrance into the Shared Savings Program for those physician practice collaborations that determine that this model best fits their practice goals. We encourage serious consideration of our above recommendations and comments. Please contact Neil Kirschner, Ph.D on our staff at 202 261-4535 or nkirschner@acponline.org if you have any questions.

Respectfully,

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

May 26, 2011

U.S. Department of Health & Human Services
Center for Medicare and Medicaid Innovation
200 Independence Avenue
S.W. Washington, DC 20201

RE: CMS-1345-P
Comments on Proposed Rules Relating to Section 3022 of the Affordable Care Act Relating to Accountable Care Organizations

To Whom It May Concern:

On behalf of the Chief Justice Earl Warren Institute on Law and Social Policy, Health, Economic & Family Security program, at the UC Berkeley School of Law ("Warren Institute"), we write in response to CMS Release No. 1345-P, in which the Centers for Medicare & Medicaid Services (CMS) of the Department of Health and Human Services (HHS) solicited comments on its proposed rules implementing section 3022 of the Patient Protection and Affordable Care Act ("Affordable Care Act") which contains provisions relating to Medicare payments to providers of services and suppliers participating in Accountable Care Organizations (ACOs).[1]

These comments will also serve as our response to:

- the Waiver Designs in Connection With the Medicare Shared Savings Program (MSSP) and the Innovation Center jointly published by CMS and Office of the Inspector General, HHS;
- Internal Revenue Service Notice 2011-20 on the MSSP;
- the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the MSSP published by the Federal Trade Commission and the Antitrust Division of the Department of Justice; and
- the Center for Medicare & Medicaid Innovation (CMMI)'s more recent proposals for an Advance Payment Initiative and Pioneer Accountable Care Organization Model.

The Warren Institute is a multidisciplinary, collaborative venture to produce research, research-based policy prescriptions, and curricular innovation on the most challenging civil rights, education, criminal justice, family and economic security, immigration and healthcare issues facing California and the nation. The Warren Institute is engaged in multiple projects concerning the implementation of

[1] *Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations*, 76 Fed. Reg. 19528-01 (proposed Mar. 31, 2011) (to be codified at 42 C.F.R. pt. 425) [hereinafter "ACO Proposed Regulations"].

health care reform and specifically working, under a twelve month grant from the Blue Shield Foundation of California, on "Breaking Down Barriers to Creating Safety Net Accountable Care Organizations." This joint project with the University of California, Berkeley's School of Public Health has been funded to examine barriers to safety net ACO formation. It is in this capacity that we write to share our views.

Safety net health care providers and the populations they serve should be prioritized as participants in the proposed implementation of the Medicare Shared Savings Program. We write because we are concerned they are not. We are persuaded that there is untapped potential within the framework of the Accountable Care Act to foster creation of a safety net delivery system-sponsored ACO model.

The health care safety net has no standardized definition, a legacy of its lack of formal structure.[2] "Generally, though, the safety net includes public hospitals and health systems, health care districts, community health centers and clinics, and for-profit and nonprofit health care organizations that provide free or discounted care."[3] In California, numerous indicators point to the fact that safety net providers serve a significant portion of our Medicare population. It is estimated, as of 2009, that 4.2 percent of California's total Medicare patient coverage is delivered in community clinics alone.[4] In addition, we know that in 2006, the Medicare Part B program accounted for approximately ten percent of total net patient revenue for licensed primary care clinics in California.[5] And community clinics in California provided health care services to nearly 199,000 patients via Medicare Part B in 2008, accounting for approximately 6 percent of total clinic revenues that year.[6]

While we are pleased that CMS has acknowledged the special role of the health care safety net in providing health care to some of Medicare's most underserved beneficiaries,[7] we offer comments to urge CMS to more fully support safety net providers in forming ACOs. Safety net health care providers serve a Medicare population that is both more complex and more expensive than the general Medicare population. This is a population ripe for integrated care innovation. We are heartened that CMS has prioritized monitoring of avoidance of at-risk patients[8] and prioritized rewarding those who serve the most complex Medicare beneficiaries.[9] It is apparent the safety net Medicare population represents both an opportunity and a challenge for CMS as it advances the Affordable Care Act's goals.

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[2] Elizabeth Saviano, California Healthcare Foundation, California's Safety-Net Clinics: A Primer 2 (2009), *available at* http://www.chcf.org/~/media/Files/PDF/S/PDF%20SafetyNetClinicPrimer.pdf.
[3] *Id.*
[4] OSHPD. *2009 Annual Utilization Data for Primary Care Clinics* (http://www.oshpd.ca.gov/hid/Products/Hospitals/Utilization/PC_SC_Utilization.html) [hereinafter OSHPD data].
[5] Saviano, *supra* note 2, at 20, *citing California Community Clinics: A Financial Profile*, Analysis of 2003-06 Annual Utilization Data compiled by OSHPD. Capital Link, in collaboration with California Healthcare Foundation, November 2008.
[6] Capital Link, California Healthcare Foundation, California Community Clinics A Financial Profile, 2005-2008 37 (2010), available at http://www.caplink.org/resources/California%20Community%20Clinics,%202005-2008.pdf.
[7] ACO Proposed Regulations at 273.
[8] 42 CFR Section 425.12(b).
[9] *See, e.g.*, 42 CFR Section 425.7(b)(4).

In the comments below, we provide support for the following recommendations:

- Include FQHCs and RHCs in ACO formation
- Alleviate operational requirements that disproportionately burden safety net providers, including cost, administrative and patient barriers
- Ensure proper checks and balances on provider concentration in safety net ACOs
- Provide financial incentives tailored to safety net ACOs
- Supply safety net ACOs with technical assistance on issues such legal barriers and health privacy
- Consider the impact of ACO regulations on smaller safety net ACOs
- Engage state policymakers and stakeholders on possible state barriers to MSSP participation by safety net providers

I. Providers and Suppliers Eligible to Form an ACO: The Exclusion of FQHCs and RHCs

Under the proposed rules, Federally Qualified Health Centers ("FQHCs") and Rural Health Centers ("RHCs") are ineligible to form ACOs[10] because each fails to collect data the rules identify as essential to the ACO assignment methodology. Specifically, data identifying the precise services rendered, the type of practitioner providing the services, and the physician specialty involved are not compiled.

Data Issues. FQHCs run afoul of the proposed rules because of a lack of a primary care Health Care Common Procedure Coding System ("HCPCS"), rendering the data inadequate for associating the rendering provider with the specific services furnished to the beneficiary.[11] The lack of the data elements necessary to determine beneficiary assignment during the performance year is based on CMS's interpretation of the statutory requirement of the identification of the provision of primary care services furnished by a physician, and the calculations of expenditures for the 3-year benchmark.[12]

This is a draconian solution to the need to standardize cost estimates across data sources, particularly when health economists have developed algorithms to match other incommensurate data sources with Medicare payment rates.[13] FQHCs now collect HCPCS codes for services[14] so this data matching function would need to be in place for only two years to accumulate the necessary baseline data. Indeed, CMS's proposal to provide beneficiary identifiable claims data to ACOs acknowledges that HCPCS- included existent data may still be imperfect for ACO goal tracking[15] and will require, in essence, the creation of a "real time" data set for all ACO participants. We recommend CMS determine ways to fully incorporate FQHCs via, for example, the already existing methods to match otherwise incompatible data sets with the needs of the Medicare program.

[10] 42 CFR Section 425.5(b).
[11] ACO Proposed Regulations at 44. FQHCs will collect HCPCS codes for services beginning in 2011 in preparation for the development of the FQHC Prospective Payment System. ACO Proposed Regulations at 45.
[12] ACO Proposed Regulations at 45.
[13] *See generally* Ciaran S. Phibbs et al., *Estimating the Costs of VA Ambulatory* Care, 60 Med. Care Res. Rev. 54S (2003).
[14] ACO Proposed Regulations at 45.
[15] ACO Proposed Regulations at 45.

Provider Issues. FQHCs make extensive use of primary care physician supervised team health care providers[16] in medically underserved areas. [17] The Medicare Claims Processing Manual acknowledges the value of this by spelling out that the FQHC encounter payment rate covers services provided by an FQHC physician, physician assistant, nurse practitioner, clinical nurse midwife, clinical social worker, and others.[18] Many FQHCs already embody, in short, a primary care model based on a multidisciplinary team approach.[19] CMS's earlier adoption of the encounter payment rate has encouraged this approach. It would be ironic to penalize with exclusion those further along the developmental timeline of more cost-effective integrated primary care for being just that.

Unique Issues to RHCs. RHCs represent a particularly compelling case for ACO formation inclusion. There are 274 Medicare Certified Rural Health Clinics in California, representing a little over seven percent of the national total. [20] There is currently little managed care penetration in California's rural areas.[21] If the promise of better integrated outpatient care is to be brought to California's rural Medicare beneficiaries, it will need to begin with RHCs. The exclusion of RHCs from those eligible to form an ACO will only serve to exclude rural providers and the populations they serve from forming efficiency-enhancing ACOs that might serve to counterbalance the inpatient service-favoring skew that has developed out of many rural preferential payment provisions.[22]

Limited role for FQHCs and RHCs is not enough. Although we acknowledge the intent to ameliorate this exclusion of FQHCs and RHCs by adding additional shared savings payments to both one-sided and two-sided ACO models that include a strong FQHC and/or RHC presence within the structure of the ACO,[23] we are not persuaded the proposed inclusion bonus programs are consistent with either the letter or the spirit of the Accountable Care Act. If FQHC participation is limited to participation only at the periphery of an ACO and if the FQHC patients may not be assigned lives for ACO benchmark and shared savings calculations, it is hard to see why any FQHC would be sought as an ACO participant. In addition, if "dually eligible" rural Medicare beneficiaries are particularly sought by CMS as ACO patient participants[24], it is difficult to imagine how this goal may be reached absent FQHC and RHC inclusion in those entities eligible to form ACOs.

The Center for Medicare and Medicaid Innovation's Pioneer Accountable Care Organization Model Request for Application ("Pioneer ACO RFA") specifically "encourages applications from ACOs

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[16] *See, e.g.,* Tim Bates and Susan Chapman, *Physician Assistant and Nurse Practitioner Staffing in California's Community Clinics: 2005-2008*, UCSF Center for the Health Professions (2010).
[17] Section 330 of the Public Health Service Act (42 U.S.C. 254b) defines federal grant funding opportunities for organizations to provide care to underserved populations.
[18] Department of Health and Human Services, Centers for Medicare and Medicaid services, Medicare Claims Processing Manual, Chapter 9, Section 20.1, CMS Pub. 100-2 (https://www.cms.gov/manuals/downloads/clm104c09.pdf).
[19] John Zweifler et al., *Creating an Effective and Efficient Publicly Sponsored Health Care Delivery System*, 22 J. HEALTH CARE POOR UNDERSERVED 311, 312 (2011).
[20] Kaiser, 2011
[21] Farra Bracht and Lisa Folberg, *HMOS and Rural California*, California Legislative Analyst's Office (2002); available at http://www.lao.ca.gov/2002/hmos_rural_ca/8-02_hmos_rural_ca.html.
[22] Eileen Salinsky & Jessamy Taylor, Nat'l Health Policy Forum, *Exploring California's Rural Health System: From the Redwood Forests to the Baja Border* at 10 (2005).
[23] ACO Proposed Regulations at 45.
[24] ACO Proposed Regulations at 119.

led by FQHCs."[25] The Pioneer ACO RFA outlines a program of modest scope, with CMS preparing to enter into participation agreements with no more than 30 organizations.[26] The requirement of 15,000 aligned beneficiaries may well rule out smaller safety net initiatives from participation in the Pioneer ACO RFA. In addition, interested organization letters of intent are due not later than June 10, 2011, or less than a month from the announcement of the Pioneer ACO RFA. We are concerned that safety net provider oriented ACOs may not be that quick out of the gate.

Conclusion. In short, FQHCs and RHCs should be included because they serve a significant portion of the Medicare population. The hurdles to participation outlined in the proposed regulations can be overcome by methods of data extrapolation, including some already used by CMS, and by the acceptance that the FQHC model of care delivery, far from being a liability, is an advantage in achieving the three-part aim of reduced costs, better care for individuals, and better health for populations.

II. ACO Operational Requirements That Disproportionately Burden Safety Net Providers

In addition to the definitional and assignment based challenges to safety net ACO formation outlined in Part I of these comments, we are concerned that additional operational requirements found in the proposed regulations also present formidable barriers to safety net ACO formation. The key to safety net ACO formation and operation will surely be in making the ACO infrastructure no more burdensome or expensive than is absolutely necessary.

Upfront Costs. We are concerned that the upfront costs, particularly for the development of electronic medical records, may preclude safety net entity formation of ACOs. We are pleased to see the Advance Payment ACO proposal under consideration. We are particularly concerned that advance payment design be made available to safety net ACOs, even if this payment model is not adopted for ACOs outside the safety net. Given CMS's plans to, for example, withhold 25 percent of shared savings payments to offset potential future losses, an Advance Payment Initiative could be crucial to the safety net's participation. Moreover, the Initiative should be structured so as to, in effect, provide the "venture capital" safety net providers clearly need, but cannot otherwise access, to participate in the MSSP.

Alternative Formation and Operation Models. The ACO application itself will require submission of formation documents, quality assurance and clinical integration standards, ACO organization and management structure, evidence of a board-certified physician medical director, and documents relating to governing body composition.[27] We applaud the flexibility demonstrated by consideration of the possibility that substitute arrangements could be offered for any of these mandatory application materials.[28] In particular, we note that the requirements of a physician-led quality assurance and process improvement committee might be particularly onerous in rural areas where the acuteness of the physician shortages is such that many physicians in community clinics are already stretched quite

[25] Department of Health and Human Services, Centers for Medicare & Medicaid Services, Pioneer Accountable Care Organization (ACO) Model Request for Application at 19 (2011) .(http://innovations.cms.gov/wp-content/uploads/2011/05/Pioneer-ACO-RFA.pdf) [hereinafter Pioneer ACO RFA].
[26] Pioneer ACO RFA at 3.
[27] ACO Proposed Regulations at 65.
[28] *Id.* at 66.

thin with care delivery and administrative responsibilities. In particular, we propose that safety net providers be offered an alternative formation and operation option for the physician-led quality assurance and process improvement committee, substituting a physician-overseen quality assurance and process improvement committee.

Impact of Unique Patient Population. Smaller ACOs may, similarly, be disadvantaged by the proposed standards for promoting patient engagement. The safety net Medicare population is a more transient population than the general Medicare population.[29] Patient engagement, in this context, may be more challenging. The fostering of health literacy in a transient population may involve attempts to promote follow up appointments, for example.[30] The problem of churn in the safety net population will be a formidable one in light of the proposal to prohibit the ACO from developing any policies that would restrict a beneficiary's freedom to seek care from providers and suppliers outside of the ACO.[31] Alignment is more flexible than assignment,[32] but it is also harder to pursue continuity of care with non-assigned beneficiaries. In addition, the requirement that ACOs develop and implement individualized care plans for targeted patient populations[33] composed of high-risk individuals could be considerably more daunting for a higher risk general Medicare beneficiary population. We urge that safety net ACOs that disproportionately serve high-risk beneficiaries be rewarded for their patient population profile with risk adjustment based on diagnostic and not only demographic information.[34]

Financial Rewards for Safety Net ACOs. We urge you to consider providing financial rewards to safety net ACO Medicare beneficiaries who participate in safety net ACO governance. CMS has proposed that Medicare beneficiaries be directly involved in the leadership of ACOs, which we applaud, but this is a tall order that should be backed by rewards for safety net providers who achieve beneficiary representation. Further rewards should be available for safety net ACOs that successfully recruit dually eligible patients for seats on their governing boards. The presence of one beneficiary on a board should be a starting point, not a maximum, and CMS should emphatically support that mandate. Just as provider financial incentives must be aligned with better outcomes, safety net beneficiary participation should be aligned with fuller participation.[35]

CMMI's Pioneer ACO Model. As noted above, the Center for Medicare and Medicaid Innovation's Pioneer ACO Model RFA offers some relief from these disincentives to safety net ACO

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[29] Lewin ME, Baxter RJ. *America's Health Care Safety Net: Revisiting the 2000 IOM Report*. Health Aff (Millwood). 2007 Sep–Oct;26(5):1490–4.

[30] In this case the prospective treatment approach the safety net Medicare beneficiary would be contemplating is the decision to continue treatment.

[31] ACO Proposed Regulations at 81.

[32] *Id.* at 142.

[33] *Id.* at 93.

[34] Mark A. Hall, Risk Adjustment Under the Affordable Care Act: A Guide for Federal and State Regulators, The Commonwealth Fund 7 (2011), available at http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2011/May/1501_Hall_risk_adjustment_ACA_guide_for_regulators_ib.pdf.

[35] Benjamin F. Springgate & Robert H. Brook, *Affordable Care Organizations and Community Empowerment*, 305 AM. J. MED. ASS'N 1800-1801 (2011).

participation. In particular, the expansion of eligible providers to include FQHCs[36] and the definition of an ACO professional's inclusion of practitioners who are physician assistants, nurse practitioners, or clinical nurse specialists[37] makes genuine room for safety net ACO participation. The allowance of non-physician primary care practitioners is consistent with the community clinic service model. The Pioneer ACO RFA outlines a program of modest scope, however, with CMS preparing to enter into participation agreements with no more than 30 organizations.[38] In addition, interested organization letters of intent are due not later than June 10, 2011, or less than a month from the announcement of the Pioneer ACO RFA.

The Pioneer Model RFA may also exacerbate one major barrier to safety net ACO participation. In particular, the requirement that there be a minimum of 15,000 aligned beneficiaries[39] discourages participation from smaller safety net providers. Alternatively, the faster track to ACO formation and participation may unwittingly promote provider concentration, not an unambiguous good in California's health care provider markets.

Conclusion. To facilitate successful ACO operation in the safety net, we recommend aggressive deployment of an Advance Payment Initiative, alternative operational standards, greater rewards for high-risk beneficiaries and beneficiary participation, and expansion of the promising Pioneer ACO Model.

III. ACO Formation and Operational Requirements That May Promote Provider Concentration

The success of Medicare ACO initiatives, whether through the Medicare Shared Savings Program or the Pioneer ACO RFA will be judged, in part, by whether these programs involve provider groups of all types, not only large integrated group practices with affiliated hospitals. This measure of success is amplified by the acknowledgement that health care providers are more likely to integrate their care delivery for Medicare beneficiaries through ACOs if they can also use the ACOs for commercially insured patients.[40] "[P]roviders' main purpose in forming ACOs may not be to achieve cost savings to be shared with Medicare but to strengthen their market power over purchasers in the private sector."[41]

Access to Specialists. Safety net providers are typically not motivated by the drive to strengthen their market power over purchasers in the private sector. They will, however, run the risk of fallout from an increasingly concentrated market for specialists. If the safety net's ultimate ACO goal is a "publicly sponsored health care delivery system that combine[s] a primary care base built around community

[36] Pioneer ACO RFA at 19.
[37] *Id.*
[38] *Id.* at 3.
[39] *Id.* at 30.
[40] Fed. Trade Comm'n & Dep't of Health and Human Serv., Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws (Oct. 5, 2010).
[41] Havighurst and Richmond, *The Provider Monopoly Problem in Health Care*, 89 OR. L. REV. 847, 872 (2011).

health centers with safety-net hospitals and the specialists that serve them,"[42] then specialists will need to play a major role in safety net ACO formation. The availability of specialists for safety net ACO participation may be diminished by the "growing frenzy of mergers involving hospitals, clinics and doctors' groups eager to share costs and savings, and cash in on the incentives."[43] We are in the midst of what has been labeled a "post-reform merger wave."[44] But what is optimal for commercial insurance may be far from optimal for ACOs in the safety net. Nascent safety net ACOs will need access to a robust roster of specialists ready, willing, and able to participate to participate in a safety net ACO through either the Medicare Shared Savings Program or the Pioneer Accountable Care Organization RFA.

Great care has been given, in the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, to limit the safety zones of independent ACO participants (such as physician group practices) to a combined share of 30 percent or less of each common services in each PSA's service area[45] but the calculation of the ACO's share of services, as outline in the document's Appendix, relies on the identification of Physician Service Areas based on retrospective ZIP code data. The PSA is a backward looking creation, in short. It tells us nothing about the willingness of important groups, like specialty physicians, to participate in Medicare going forward and whether those continuing to participate in Medicare are willing to serve a safety net population. A number of California specialty physicians, for example, accept Medicare only with the supplement of a substantial Medicare patient annual fee,[46] a requirement unlikely to make them accessible to the safety net patient population. CMS should counter this potential obstacle with rewards and/or incentives for specialists who participate in ACOs with safety net providers.

Conclusion. We acknowledge that a number of the problems with identifying providers willing to accept new Medicare safety net beneficiaries are beyond the scope of the Medicare ACO enterprise. But we are persuaded that nothing done to establish the program should worsen pre-existing problems with safety net Medicare provider participation. Therefore we recommend incentives and/or rewards for specialists who collaborate with safety net providers, and we urge the adoption of a rule that excludes all Medicare providers who require supplemental annual fees from the calculation of available specialists.

IV. Provider Compensation and the Medicare ACO Proposed Rule

Fraud and Abuse Waiver Designs. CMS has specifically solicited comment on the necessity for waivers for arrangements related to establishing the ACO when closely related to ACO formation,

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[42] John Zweifler et al., *Creating an Effective and Efficient Publicly Sponsored Health Care Delivery System*, 22 J. HEALTH CARE POOR UNDERSERVED 311, 316 (2011).
[43] Havighurst and Richmond , *supra* note 42 at 850 *n.*7, *citing* Robert Pear, *Consumer Risks Feared as Health Law Spurs Mergers*, N.Y. TIMES, Nov. 20, 2010, http://www.nytimes.com/2010/11/21/health/policy/21health.html.
[44] Tim Greaney, *Accountable Care Organizations and Antitrust: A New PSA Test* (April 1, 2011); available at http://www.healthreformwatch.com/2011/04/01/a-new-psa-test/.
[45] *See* Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program at 7.
[46] Christopher Weaver, *As Medicare Pay Shrinks, Some California Docs Hike Patient Fees* (March 16, 2010), http://www.npr.org/blogs/health/2010/03/calif_heart_docs_hike_patient.html

compliance with MSSP regulations, or building IT or administrative capacity. As with any legal issue, one of the special challenges safety net ACOs will have to face in forming and then operating an ACO is capacity. Not only does the proposed regulations' requirement of an added compliance official[47] potentially drain safety net providers' coffers, but the addition of new regulations that require research and advice could also mean an increased financial burden for the safety net. The proposed fraud and abuse waiver designs are no exception. Therefore, CMS should consider whether safety net providers should be permitted to substitute another professional, such as a general counsel or head of administration, in the compliance official role.

There will be substantial legal work to do in the initial years of the program. For example, the phrase "necessary for and directly related to" will no doubt require interpretation by CMS, OIG and providers themselves before a working definition emerges. In a larger example, financial relationships other than shared savings payments, in order to be legal under the proposed waivers, must meet an existing exception to the Stark laws. Many such exceptions exist, such as bona fide employment relationships, personal service relationships and indirect compensation arrangements. However, obtaining solid legal advice about the new types of financial relationships that will form under the MSSP may require more legal resources than safety net providers have previously enlisted. Thus, there is a chance that, in spite of the proposed waiver designs, legal issues like fraud and abuse may prove to be obstacles or disincentives to safety net ACO formation. CMS should consider whether it can offer technical legal assistance, such as CMS or HHS-OGC attorneys, to assist safety net providers in navigating this facet of the MSSP.

Additional Needed Waivers. CMS is soliciting comments regarding additional waivers that would be necessary to carry out the provisions of the MSSP. Among the issues discussed is the use of existing exception and safe harbor for electronic health records (EHRs) arrangements. Although safety net providers are making progress with regard to EHRs, much work remains to be done. In California, for example, while almost half of the state's community clinics have implemented EHRs, one in ten have yet to even start the EHR process.[48] To ensure that anxiety about fraud and abuse laws does not impede the process, CMS and OIG should act affirmatively to guarantee the future of the present exception for EHRs.

In section II.B.9.d. of the discussion of the proposed rule, CMS notes that the provision of any free services between parties (such as ACO participants) in a position to generate Federal health care program referrals could trigger evaluation under fraud and abuse laws. "Processes to coordinate care" are statutorily mandated for the MSSP, and safety net providers may be more likely than others to share resources such as case managers and telehealth without charge. CMS should examine whether a specific waiver should be adopted to eliminate any disincentives for this type of activity where it serves the three-part aim of the MSSP.

[47] 42 CFR Section 425.5(d)(10)(i)(A).

[48] Murchinson, et al., *For the Record: EHR Adoption in the Safety Net*, California HealthCare Foundation, February 2009; available at http://www.chcf.org/~/media/Files/PDF/E/PDF%20EHRAdoption.pdf.

CMS has also solicited comment on distributions of shared savings or similar payments received from private payers. The fair competition guidelines issued by the FTC and DOJ are expressly aimed at "ACOs that participate in both the Medicare and commercial markets,"[49] and we believe CMS would do well to similarly integrate guidance to ACOs in other relevant arenas, notably Medicaid, in the proposed fraud & abuse waiver designs. This may help ensure that as many patients as possible reap the benefits of accountable care.

The MSSP proposed rule makes a limited number of additional references to fraud and abuse as justifications for certain proposed regulations. The proposed rule references, as one of the reasons retrospective beneficiary assignment is preferable, the potential for improper "inducements to overutilize services or to otherwise increase costs" for Medicare beneficiaries not assigned to an ACO. In other words, CMS was concerned that ACOs could, in a sense, "hide" expenses by associating them with beneficiaries for whom the ACO is not accountable via the MSSP.[50] This perfectly illustrates the continuing need for fraud and abuse laws. We agree that fraud and abuse laws should be, as CMS has proposed to do, waived in necessary circumstances, not repealed. And retrospective beneficiary assignment not only prevents the form of abuse described above, but also protects patient populations as a whole from the selective delivery of quality care.

Conclusion. Fraud and abuse laws play a vital role in the Medicare system, but waiving them for MSSP payments and in other circumstances, as CMS has proposed to do, is equally essential to the success of the MSSP. We recommend CMS consider relaxing a limited number of its governance regulations for the safety net, and that you offer technical assistance to help safety net providers navigate the new waivers. We also recommend CMS explore additional or more durable waivers for EHRs arrangements and processes to coordinate care. Finally, we recommend CMS consider offering guidance on the applicability of the MSSP fraud & abuse waivers to similar programs in Medicaid.

V. Concerns Associated with Safety Net Patient Populations/Regions

Allowances for Safety Net. Health providers for the safety net know that safety net populations have special needs and circumstances that are sometimes overlooked. CMS has made some proposals for the MSSP that will benefit providers who treat patients in the safety net. For example, CMS has indicated outcome and patient experience measures "should be adjusted for risk or other appropriate patient population or provider characteristics."[51] CMS has proposed to truncate beneficiary expenditures at the 99th percentile, and will not remove IME and DSH payments from the per capita costs included in the benchmark for an ACO. They are exempting small ACOs from the 2 percent net savings threshold and permitting them to share on first dollar savings under the one-sided model. We are pleased that that these provisions are present in the proposed regulations.

[49] *See* Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program at 1.
[50] A similarly-aimed, but inverse, part of the proposed rule protects beneficiaries by prohibiting an ACO from avoiding at-risk patients. *See, e.g.,* ACO Proposed Regulations at 21.
[51] ACO Proposed Regulations at 13.

Rewards for Successful Responses to Diversity. In addition, CMS has proposed to require ACOs to describe how they will partner with community stakeholders, and address diversity. Where diversity is concerned, safety net patient populations are like any other patient population in America—"only more so." Therefore, safety net providers may need additional capacity to address issues such as language and compliance with provider instructions (issues which are, of course, interrelated). The challenge of serving particularly diverse Medicare beneficiary populations is endemic to the ACO program—found as well in the challenge of developing and using culturally appropriate shared decision making tools[52], for example. Safety net ACOs that embrace these goals and perform to standard deserve additional compensation.

Issues with Assignment and Participation. The nature of providing for the health care of the safety net may also mean a bumpy road for ACO providers, particularly at the beginning. ACOs may need to bolster capacity mid-stream. Thus, CMS may need to reconsider its prohibition on adding ACO providers to an ACO during the 3-year agreement period. In addition, assigning beneficiaries solely to physicians designated as primary care providers may make it difficult (as CMS concedes) for ACOs to form in some geographic regions with such primary care shortages.

Conclusion. While the proposed regulations make some allowances based on the type of populations treated by an ACO, they should consider further rewards. CMS should also re-examine some provisions regarding how beneficiaries are assigned to ACOs, and when ACO providers can be added to an ACO, in order to best facilitate successful ACO formation in the safety net.

VI. The Medicare Shared Savings Program and Privacy

The Proposed Rule discusses HIPAA and, to a lesser extent, the Privacy Act of 1974.[53] Generally, the Rule's treatment of HIPAA is wise because it anticipates potential problems before they arise. For example, the Rule discusses at length that while ACO participants and ACO providers/suppliers are "covered entities" that must adhere to HIPAA, HIPAA permits disclosure of "the four identifiers" (name, DOB, sex and HIC) for "health care operations" purposes. CMS also proposes to proactively ensure that an appropriate Privacy Act system of records "routine use" is in place prior to making any disclosures, in order to avoid running afoul of the Privacy Act. The proposed rule even includes a data use agreement (DUA) that ACOs would have to accept to participate in the MSSP.

Without a doubt, this advance legwork is needed. Not only does the proposed rule specifically mention that some types of data use that could implicate HIPAA, but still other types of data mentioned in the proposed rule may present challenges in the future. For example, the proposed rule contemplates stepping up data collection on not only patient experience, but measures of caregiver experience.[54] We believe that as these measures expand, so too must CMS's vigilance in clearing the logistical and legal way for achieving the three-part aim.

[52] 42 CFR Section 425.5(d)(15)(ii)(B)(3).
[53] *See, e.g.,* ACO Proposed Regulations at 117.
[54] *See, e.g.,* ACO Proposed Regulations at 195.

The Need for More Education. Research shows that health care providers are often anxious to a fault about complying with the provisions of HIPAA, and that safety net providers are no exception.[55] But more than anxiety, we have seen how HIPAA actually can prevent providers from acting--and enforcement agencies as well. CMS must act to ensure HIPAA does not paralyze participants in the MSSP. The DUA, and other safeguards, will ensure the protection of private information (as will the option for patients to opt out of data sharing).

Conclusion. We suggest CMS and CMMI should mount a substantial education campaign to inform MSSP participants about the requirements of HIPAA and the Privacy Act, with the specific goal of ensuring that needless anxiety about HIPAA does not interfere with work toward the three-part aim.

VII. The Medicare Shared Savings Program and State Law

State Regulation of Risk Bearing Entities. CMS notes they do not intend for the MSSP to render States responsible for bearing any costs resulting from its operation. But they acknowledge that "some States may regulate risk bearing entities."[56]

Indeed, the California Department of Managed Health Care (DMHC) announced in January their intention to regulate ACOs, and elaborated at a recent meeting.[57] The Department's jurisdiction is triggered when any person undertakes to arrange for the provision of health care services to subscribers or enrollees, or to pay for or to reimburse any part of the cost for those services; and is compensated based on a prepaid or periodic charge paid by or on behalf of the subscribers or enrollees. At the moment, the California DMHC has taken the position that ACOs under the MSSP are not subject to their licensure requirements due to the fact providers are still paid on an FFS basis.[58] The California DMHC has not yet taken a position on the partially capitated ACOs outlined in the Pioneer ACO RFA. Yet in the state's health care system as a whole, ACOs are on notice that California may regulate them.

State Law and ACO Governance. Among other additional state law impacts, CMS notes in its proposed rule that state law may be implicated by the regulations' requirement that ACOs have a Medicare beneficiary on their governing boards. CMS also seeks comment on the degree to which state insurance laws may be implicated by the regulations. The greater the legal barriers to participation in the MSSP, the less likely health providers are to participate—especially safety net providers lacking the capacity or confidence to enter new legal arenas.

Conclusion. CMS should begin discussions with state policymakers and other stakeholders now to ensure that the MSSP can go forward and that state laws and regulations do not serve as additional disincentives to MSSP participation by safety net providers.

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[55] *See, e.g., The Impact of Fear of HIPAA Violation on Patient Care.* Touchet BK, Drummond SR, Yates WR. PSYCHIATR SERV. 2004 May;55(5):575-6.
[56] ACO Proposed Regulations at 310.
[57] California Department of Managed Health Care, Accountable Care Organizations Oversight Impelementation (May 19, 2011). Available at http://www.dmhc.ca.gov/library/reports/news/fssbacooi.pdf.
[58] *Id.*

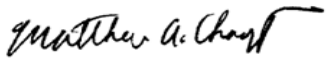
VIII. Conclusion

The Medicare Shared Savings Program is a major step on a promising path toward improvement of health outcomes for all Medicare beneficiaries. Safety net patients, far from being at the periphery of health care reform, need its benefits the most--and also offer providers the chance to create savings via well-coordinated care by ACOs.

We respectfully request the Centers for Medicare & Medicaid Services of the Department of Health and Human Services, the Center for Medicare & Medicaid Innovation of the Department of Health and Human Services, the Federal Trade Commission, the United States Department of Justice, and the Office of Inspector General of the United States adopt final regulations for the Medicare Shared Savings Program consistent with our recommendations.

Sincerely,

Ann Marie Marciarille
Senior Research Fellow, Berkeley Center on Health Economic & Family Security



Matthew A. Chayt
Legal Fellow, Berkeley Center on Health, Economic & Family Security

To the CMS Innovation Center & related HRSA projects:

The difficulties for the FQHC "look-alike" community health centers in attempting to participate, collaborate and be involved in the current new CMS initiatives are huge. All of us in community health and public health who are true to our mission support Dr. Berwick's ideas and efforts. We deeply believe in and want to be part of beneficial reform to improve care and reduce the negatives of service duplication, high costs, unnecessary hospitalization and inefficiencies. But you all must understand that the "look-alike" community health centers have not benefitted from recent federal grants and ongoing federal assistance that the Federally Qualified Health Centers have received. We, the "look-alikes" are struggling financially, with large reductions in grants, and pending severe reductions in Medicaid. These reductions and lack of support impact services, programs, outreach and education for patient groups, staffing and the prevention of disease, as well as effective care of patients with chronic conditions and ongoing needs..

In addition, the recent HRSA decision to not review and consider the applications we worked for months to write and submit, that would have given us the opportunity to become full Federally Qualified Health Centers (FQHCs) is a terrible blow. To raise the bar of improved quality of care, ask (and soon require) that the "look-alike" health centers meet all of the new standards for cost efficiency and improved quality that the FQHCs and high-end private practices meet, without receiving any support and incentives designed to help that occur, just sets up a large number of committed health centers to struggle and many to fail. The low-income diverse communities we serve, inner city and rural, also need to be connected to the best clinical services, patient education and team-oriented care.

This will only happen with positive reform across the board, that benefits all capable provider groups, and that includes community health centers with look-alike status. HRSA and CMS (especially the Innovation Center) need to consciously support and design incentives, and provide some federal assistance for the 330 "look-alike" community health centers." Please do not continue to exclude us. It works against everything positive worthwhile reform should be doing.

I hope that you will have someone respond to my request, and that you will forward this to Dr. Berwick.

Sincerely,
Carol Rodman

Carol Rodman MA MPH
Special Projects Director
Upham's Corner Health Center

Dear Sir/Madam

I have a few comments on the idea of giving advanced payment to potential ACOs:

Doesn't it seem that the three year agreement period may be too little of a time to turn initial capital granted to a potential ACO by Medicare into a system that is truly cost-efficient and effective? I had some doubts in this short time window before, but now that taxpayer money is expected up front, I am more seriously concerned. Is there some kind of accountability in place for this money?

Zachary Williams