PREMIER

October 19, 2010

Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

Re: Medicare Shared Savings Program.

Dear Dr. Berwick:

On behalf of the Premier healthcare alliance serving more than 2,400 leading hospitals and health systems and 70,000-plus other healthcare sites, we would like to provide guidance to the Centers for Medicare & Medicaid Services' (CMS) formation of Accountable Care Organizations (ACOs), per the Patient Protection and Affordable Care Act (ACA) of 2010. Premier, a 2006 Malcolm Baldrige National Quality Award recipient, maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks. Our comments primarily reflect the concerns of our owner hospitals and health systems. As service providers, the members of our alliance have a vested interest in the effective operation of ACOs. This is particularly true of the nearly 75 health systems participating in our ACO Implementation Collaborative, launched in May 2010.

Note that the attachments to this letter contain proprietary information. Please do not publicly display or share the attachments without the express agreement of Premier Inc.

BACKGROUND

The Premier healthcare alliance believes that, as a nation, we all must work to rein in spiraling U.S. healthcare costs, expand access, promote wellness and improve the consistency of quality outcomes. We know we need to move from a disjointed, siloed "system" of delivery to one that is better coordinated and

12255 El Camino Real
Suite 100
San Diego, CA 92130

T 858 481 2727
F 858 481 8919

2320 Cascade Pointe Blvd (28208)
P.O. Box 668800
Charlotte, NC 28266-8800

T 704 357 0022
F 704 357 6611

3600 Market Street
7th Floor
Philadelphia, PA 19104

T 215 387 9401
F 215 689 9406

444 N Capitol Street NW
Suite 625
Washington, DC 20001-1511

T 202 393 0860
F 202 393 6499

premierinc.com

aligned to provide real *value* to patients, providers and payers alike. But, this requires a new vision, new culture, and new practice—none of which are easy to achieve in healthcare.

Statistics show healthcare costs have been growing at an unsustainable rate, reaching an estimated 17.3 percent of the Gross Domestic Product (GDP) in 2009, according to CMS. This represents the largest one-year increase in history. CMS predicts that, left unchecked, costs will rise to 19.3 percent by 2019 — comprising almost one-fifth of the nation's GDP and nearly four times the 5.1 percent of GDP that healthcare consumed in 1960.[i] At the same time, research and anecdotal reports continue to identify gaps and inequities in the quality of healthcare delivered in the United States.

These trends — coupled with the millions of Americans still un- or underinsured — led to health reform, the most major change to U.S. health policy since the passage of Medicare and Medicaid in the mid-1960s. Now, the challenge is to transform the national infrastructure from a volume- to a value-based model that better aligns the incentives and needs of all stakeholders. The goal is to provide more-coordinated, higher-quality healthcare more cost-effectively, while expanding access to services to an estimated 32 million Americans.

While still evolving, the concept of Accountable Care Organizations (ACOs) is gaining ground and, we believe, is a way to overcome the challenges outlined above without rationing care or dramatically increasing taxes. ACOs are designed to closely connect groups of providers who are willing and able to take responsibility for improving the overall health status, care efficiency and experience for a defined population.Thus, ACOs can overcome the fragmentation and volume orientation of our existing fee-for-service system so that we more appropriately incent health and wellness, rather than treatment for illnesses. Achieving these incentives, will "bend the cost curve" and revolutionize how care is paid for, provided and received.

More than 75 member healthcare systems have already started this journey with Premier to accelerate the development of innovative models for delivering care in the private sector with the goal of participating in the Medicare ACO program as soon as it is operational.

PREMIER'S ROLE

Premier and its member hospitals have long been at the leading edge of developing, measuring and delivering effective, efficient healthcare. Based on years of experience with successful collaboratives, the Premier alliance has developed a proven model for the collaborative execution of common goals. Premier leveraged this model to achieve transformative results in quality, cost and operating metrics with the Hospital Quality Incentive Demonstration™ (HQID), a six-year joint project of 250 Premier alliance members and CMS that achieved dramatic and

sustained quality improvement and set the foundation for enhancing the science, art and methodology of process improvement in healthcare.

Next, the alliance created its QUEST®: High-Performing Hospitals collaborative, a broad-based, innovative effort of nearly 200 not-for-profit hospital members across 31 states. The program, now in its third year, is enabling participants to learn from top performers and develop and implement systemic improvements across their organizations that rapidly raise the bar in quality, efficiency and safety in the complex task of caring for patients.

Now, building on HQID and QUEST as the foundation for success and extending the methods for improvement across the continuum of care, Premier is spearheading two large-scale collaboratives: the ACO Implementation Collaborative is comprised of 24 hospitals and health systems that have or intend to enter into private-sector ACO contracts in 2011. The ACO Readiness Collaborative includes 50 systems that are building the necessary components and actively considering the move to ACO status. Both collaboratives will aid in providers developing all of the key capabilities needed to operate an effective ACO. Based on our experience thus far with our members, we provide guidance in this letter that we believe will be helpful to CMS as it formulates the proposed regulations governing the new Medicare ACO program.

PREMIER'S ACO MODEL

The Premier healthcare alliance believes the three main goals of ACOs for a defined patient population are:

A Blueprint for Building Key Components of Accountability

* ACO model graphic property of Premier Inc.

1. Measurably improve the health of populations,
2. Enhance the experience of care, and
3. Reduce total costs.

These goals are consistent with Section 3022 of the ACA, which authorizes the creation of the ACO program under Medicare, and requires ACOs to adhere to a defined "processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care." Without balancing all three facets, ACOs cannot achieve true "value" and risk unintended consequences for all stakeholders. These goals should drive the design of ACOs and be central to the measurement of their success. At left in graphical form and described later, we share Premier's vision of how

ACOs can successfully achieve full accountability for overall outcomes and efficiencies as embodied in our goals and outlined in the law:

- Build people-centric systems of care including enhanced primary care;
- Improve quality and cost for delivery-system components;
- Coordinate care across participating providers;
- Use IT, data and reimbursement to optimize results;
- Build payer partnerships and accept accountability for total cost of care;
- Assess and manage population health risk; and
- Be reimbursed based on savings and quality.

The Premier collaborative members are building these core components into the design of their ACO programs and believe that CMS should require such efforts within its ACO contracts. Particularly, CMS should adhere to the following core principles within its program:

People-Centered

People, not patients, should be at the center of the ACO. The goal is to optimize the health of communities, and this cannot be achieved with disconnected perspectives that lead to unnecessary care. We must focus on prevention and wellness through redesigning the care system to include care coordination and patient engagement. Beneficiaries should be educated to become active participants in their care, resulting in higher satisfaction and self-accountability for health. Beneficiary navigation should be provided to help people obtain appropriate care when and where they need it, and care should be tailored to meet individual needs.

Enhanced Primary Care

Health homes, also known as medical homes, are the fundamental building blocks of strong ACOs, and beneficiaries should see them as their first stop for all non-emergent care. Systems should be altered to efficiently offer care that is consistent and not episodic. This can be done through reliance on evidenced-based care practices, use of information technology, enabling staff to practice at the "top" of their licenses and alignment of payment incentives. A renewed emphasis must be placed on increased training and salary re-alignment of primary care providers in order to achieve the goals of more comprehensive and cost-effective care. An increase in the numbers of well trained and highly competent primary care providers will be necessary to achieve the three goals of ACOs.

Coordination Across the Continuum

In an ACO, people should be partners working with a designated care team to manage and improve their health across all settings of care. People must be assisted in navigating the healthcare system so they get the right care, from the right provider at the right time. This should involve having a central care team that can identify problems and intervene early, before

problems arise and hospital care becomes necessary. ACOs should incent greater provider integration, as care givers will be encouraged to work cooperatively across the care continuum to assist patients in reaching health goals and achieving common measures of success.

Data Driven and Transparent

To be successful, ACOs must understand the population they are serving and make effective use of data. This includes risk modeling, identifying patients who may benefit from targeted interventions, informing and evaluating quality improvement initiatives, identifying gaps in care, coordinating care and monitoring spending. Access to data and the ability to harness such data is critical. Moreover, transparency of the results is key. We found through the Premier HQID project with CMS that transparently sharing performance data, coupled with financial incentives, allows for the greatest learning and improves outcomes.

Participation of Multiple Payors

In order for the benefits of ACOs to be fully realized and for the lessons to be scalable to as broad a patient population as possible, CMS should be able to join existing ACOs that might include private payers, employers and Medicaid, and not just be limited to the Medicare program. The key is that practice transformation needs to occur at a community level and not a national level only. Making CMS a flexible partner with other payors makes the best use of the beneficiary volume offered by the Medicare population. For healthcare practices to transform, providers face additional costs for staff, technology and other resources, and are more likely to be successful if all payers are aligned in their new approaches to payment. Participation of other payors also will encourage diversity in approach, allowing providers to test multiple paths to ACO development. This will, in turn, offer important synergies that will accelerate identification of best practices, allowing learning healthcare systems to improve more rapidly.

Leadership

Lastly, but most importantly, ACOs must demonstrate commitment from the staff level to the chief executive, including administrative and medical leadership. The ACO structure requires a paradigm shift. Organizations can only transform successfully with expansive vision, extraordinary commitment and significant effort. The Premier alliance, for example, requires the leadership within its collaborative participants to formally attest their leadership commitment to participation. CMS will need ACOs to adequately demonstrate their ability to lead through change.

STRUCTURE

Many organizations have offered opinions of how ACOs should be structured. MedPAC proposed that an ACO "would consist of primary care physicians, specialists and at least one hospital," and suggested that it could be formed from an integrated delivery system, a physician-

hospital organization or an academic medical center.[ii] Stephen Shortell and Lawrence Casalino suggest five different models of an "Accountable Care System," (their term for an ACO): a Multispecialty Group Practice; a Hospital Medical Staff Organization; a Physician-Hospital Organization; an "Interdependent" Practice Organization; and a Health Plan-Provider Organization or Network.[iii] This listing compares with the types of organizations considered by the Congressional Budget Office's to be "Bonus-Eligible Organizations": "physicians practicing in groups, networks of discrete physician practices, partnerships or joint ventures between hospitals and physicians, hospitals employing physicians, integrated delivery systems, or community-based coalitions of providers."[iv] Despite varying perspectives, there is agreement that many organizational models, particularly those that include hospital participants, could be successful as ACOs. **We urge CMS to take advantage of its authority to recognize many different structural models.**

The ACA requires a formal legal structure to receive and distribute shared savings to participating providers. It further recognizes certain providers as eligible to participate in ACOs:

- Hospitals employing ACO professionals;
- ACO professionals in group practice arrangements;
- Networks of individual practices of ACO professionals;
- Partnerships or joint venture arrangements between hospitals and ACO professionals; and
- Other groups of providers that the Secretary deems appropriate.

While ACOs could be organized or structured in a variety of different ways, there are two broad categories:

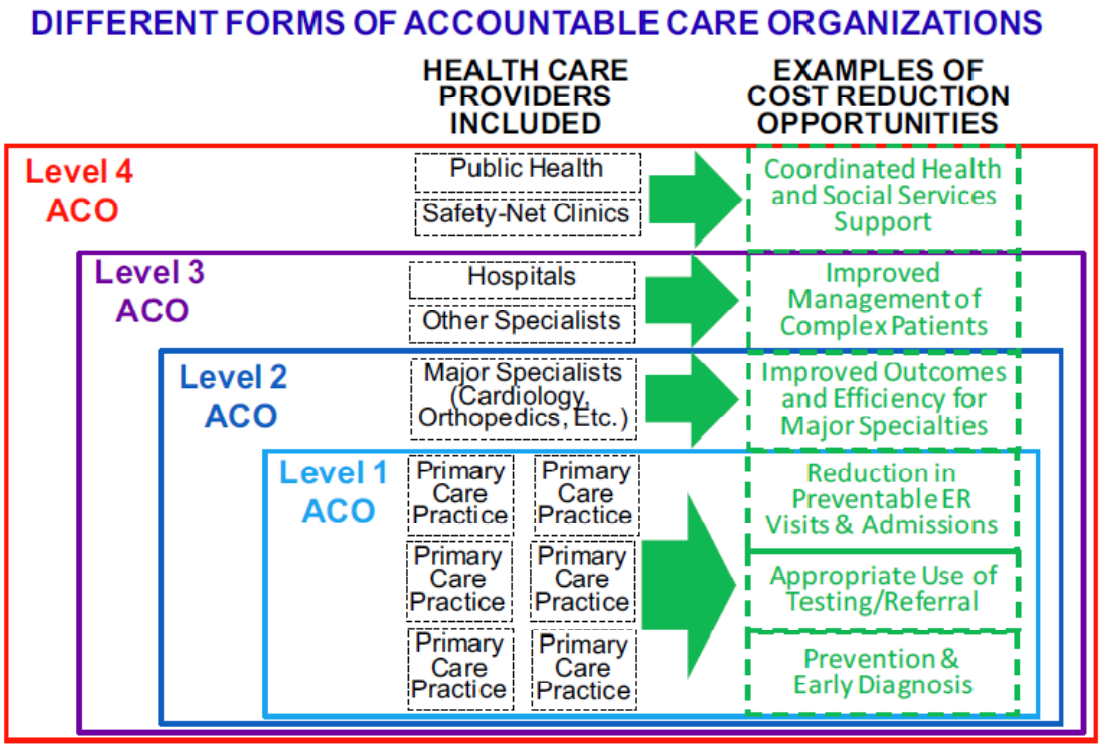
- ACOs could be single economic entities, as defined under the *Copperweld* doctrine (e.g., a hospital and its employed physicians, perhaps including other owned ancillary providers; a health system consisting of several hospitals and their employed physicians; etc.)
- Alternatively, the ACO could include multiple entities, such as physician network joint ventures or multi-provider networks as described in Statements 8 and 9 of the Statements of Antitrust Enforcement Policy in Health Care (Policy Statements) jointly issued by the Department of Justice (DOJ) and the Federal Trade Commission (FTC).

It is our belief that it is not necessary for a "clinically integrated" provider network—and, by extension, an ACO—to be a single, co-owned legal entity comprised of physicians and/or hospitals whether under Medicare or in the private sector. We believe that accountability requires coordinated relationships, not necessarily corporate integration. A "collaborative arrangement" based upon a contractual relationship among the ACOs owners and participants should be an acceptable "model" for an ACO, although subject to further analysis of its size and operational characteristics if operating in the private sector. **Premier urges the FTC and DOJ to confirm**

that such "collaborative multi-provider network arrangements" are acceptable whether within the Medicare and Medicaid programs or in the private sector.

The final ACA language expressly permits models with hospitals as the leading entities. We believe that this is crucially important to the **prospects of successful ACO formation, since in many cases the hospital will be the *only* entity with sufficient infrastructure, staff, capital risk-tolerance and other resources needed** to drive large-scale change. However, it is important to note that many not-for-profit health systems do not fit into the two hospital-lead models enumerated in ACA. That is, they neither directly employ physicians nor are engaged in partnerships or joint ventures with physicians. In many such cases, physicians are employed by a separate not-for-profit physician organization or have an independent contractor relationship with a not-for-profit medical foundation. These approaches are particularly prevalent in states with laws that preclude direct employment of physicians under the corporate practice of medicine doctrine, and areas in which the preponderance of physicians practice in small groups. By providing maximum flexibility in the approved ACO structures, CMS will most certainly increase the size of the program. **CMS should use the authority granted to it under the ACA to recognize ACOs comprised of hospitals and affiliated ACO Professionals as eligible to participate in the Medicare ACO program.**

Premier believes that CMS should seek ACOs that agree to joint accountability across the full continuum of providers. While few organizations can currently achieve a level 4 ACO as described in this graphic, that should be the ultimate goal, and preference should be shown to those closest to achieving that state.[v]



ACOs that bring doctors, nurses, hospitals and other care providers such as mental health providers, nursing homes and home health agencies together to share responsibility for keeping patients healthy will be the most transformational in the long run. **To have the maximum impact on communities and overall healthcare spending, CMS should give preference in its contracting to ACOs that are able to include the broadest group of provider types.**

Another important dimension is participation across payor types. Many of the Premier alliance members are already participating in shared savings or other alternative payment mechanisms in the private sector. To maximize results, it is critical for the ACO to align as much of its business as possible to new care and payment models. This will improve the chances of success, as the incentives to transform from volume-based strategies to value-based ones will be stronger. Bringing Medicare and private sector payment models into alignment, to the extent possible, will create synergies resulting in even higher quality and lower costs. We acknowledge that CMS will have to strike a balance between meeting the needs of the providers, beneficiaries and administrative constraints. **However, we urge CMS to allow flexibility within its contracts to tailor agreements to the market at hand and join existing arrangements.**

The organizations that are already functioning like ACOs in the private market should provide CMS with some confidence that the programs would be even more successful with the addition of the Medicare population. In these cases, the infrastructure, relationships with physicians and other providers, internal clinical and financial capabilities and information technology systems are already built. These organizations will have the quickest and smoothest transition into the Medicare ACO program, and will be best able to work through the inevitable hurdles of a new program. In particular, those working with provider-sponsored health plans will be more effective at collecting and sharing data, as well as aligning the interests of providers. **CMS should use the authority granted under ACA to give preference in awarding Medicare ACO contracts to those organizations already contracting with private payors and employers under such a model or similar alternatives.**

CMS should take steps to encourage more than one ACO in an area. Multiple ACOs will enhance competition that will drive even better results for beneficiaries and Medicare. **CMS should allow multiple qualified ACOs in markets to enhance the effect of the model and market concentration.**

CLINICIANS

Clinical Capacity

The ACA requires a sufficient number of "ACO professionals" to care for a minimum of 5,000 Medicare beneficiaries assigned to the ACO. There is no guidance, however, on how this capacity should be measured. **CMS should clearly specify flexible criteria in its Notice of Proposed Rulemaking (NPRM) to determine if an ACO has an appropriate number of ACO professionals to care for such a population.**

ACO Professionals

By specifying "ACO professionals," we believe the law gives CMS the authority to include other types of practitioners, to the extent that they satisfy the state licensure requirements, such as physician assistants (PA), nurse practitioners (NP) and certified nurse specialists (CNS) in beneficiary attribution. The ACOs should be able to provide CMS with a list of professionals for use in beneficiary assignment and the determination of sufficient clinical capacity. If they so choose, ACOs should also be able to share bonus funds not only with these practitioners, but also with others who are integral to care. While these practitioners are unlikely to be able to convene an ACO on their own, they will be key in developing a strong enough primary care base particularly in rural and shortage areas. Moreover, many integrated delivery systems make significant use of these non-physician professionals. Including them in the attribution process will improve the accuracy of attribution and will more accurately reflect the reality of such systems. **CMS should actively recognize PAs, NPs and CNSs as part of the attribution process, and allow broader inclusion of professionals in reward sharing programs.**

CMS cannot currently distinguish the specialty of physician extenders such as PAs, NPs and CNSs. This information will be necessary during the attribution process if CMS is to focus on those physicians or extenders who are serving in a primary care role. **CMS should alter the Provider Enrollment, Chain and Ownership System (PECOS) process to capture the ACO professionals' specialty designations.**

Medical Home

The Premier collaborative members are constructing their ACOs with "health homes," sometimes called medical homes, to support the people at the center. It is our belief that these are core components to successfully enhance primary care and reorienting care around wellness and care management of both acute episodes and chronic illness. The National Committee for Quality Assurance (NCQA) defines a primary care medical home as "a model of care that strengthens the physician-patient relationship by replacing episodic care with coordinated care and a long-term healing relationship."[vi] The standards include: access and communication; patient tracking and registry functions; care management; patient self-management support; electronic prescribing; test tracking; referral tracking; performance reporting and improvement; and advanced electronic communications. **CMS should incorporate these basic principles within its contract requirements, but should not initially require certification.**

Because of the up-front capital needed to restructure, CMS should allow ACOs to receive medical home payments through demonstration programs. CMS is in the process of establishing three demonstrations: 1) the Multi-payer Advanced Primary Care Initiative; 2) the Medicare Medical Home Demonstration; and 3) the Federally Qualified Health Center Advanced Primary Care Practice Demonstration. Participation will better prepare ACOs for success as they work to meet the requirements of those programs. It will also increase their short-term cash flow, allowing ACOs to reinvest those dollars in their transformation. CMS could test the medical home concept within an ACO versus within the standard FFS program, and may find that the combination of the two programs creates synergies that accelerate progress toward improved quality and reduced total beneficiary spending. **CMS should allow ACOs to participate in the medical home demonstration programs.**

BENEFICIARIES

Transparency

We believe it is critical for CMS to explain the ACO model to beneficiaries, , notify them that they have been assigned to a certain ACO and describe what affect it may have on their care. Medicare has had a long-standing history of transparency in programs such as Medicare Advantage, and should continue this exchange of information in the ACO program. The first contact with the beneficiary should be from "Medicare" as the trusted entity, and should explain who may be contacting them, why and what to expect. This will also help protect beneficiaries

against fraudulent schemes. **We recommend that CMS provide educational materials about ACOs to beneficiaries, including the name of the ACO to which they are likely to be assigned.**

Beneficiaries should be given the opportunity to withdraw from the program. If they do not, then it should be considered consent to participate and allow preliminary assignment to the ACO (in some models final assignment will be retroactive, as discussed later). Beneficiaries should then be provided special identification cards to signal to providers their "enrollment" and any special billing instructions. This will not "lock" the beneficiary into the program in any way. They can withdraw their consent at any time (which should be detailed on the card) and they can still seek care from any Medicare provider they choose. This also will provide a vehicle for getting approval for the use of personal health information, and supply providers with important information on beneficiaries at the point of care. **CMS should create an annual beneficiary opt-out process and provide program-specific identification cards to participants.**

Moreover, because the model does not place any obligations on the beneficiary to remain within the ACO "network," unlike many of the emerging private sector models, knowledge of the program and its goals may encourage beneficiaries to be more engaged. We believe it is vital that ACOs be able to contact beneficiaries directly about their care. Information provided would not be marketing materials. Instead, ACOs may want to institute programs like medication or procedure reminders, offer in-home technologies, provide educational materials or simply check in on a beneficiary post hospital discharge. **We urge CMS to allow ACOs to directly contact beneficiaries with opportunities to improve their health without prior approval from CMS.**

Beneficiary Protections

The ACA requires ACOs to "define processes to promote evidenced-based medicine and patient engagement, report on quality and cost measures, and coordinate care such as through the use of telehealth, remote patient monitoring, and other such enabling technologies."

We expect that CMS will build in a number of beneficiary protection policies within the ACO program, including rules around contacting the beneficiaries directly (see above), the payment structure within the ACO (See "Legal" section) and monitoring quality metrics (See "Value Metrics" section). We believe that the ACO structure is well conceived to avert any unintended consequences on beneficiaries through these means. To identify where ACOs should focus to reduce disparities in care within the population and improve overall health, the **ACOs should be required to conduct assessments of beneficiary social, cultural, literacy and mental health status in addition to medical risk as part of the contract.**

CLINICAL AND ADMINSITRATIVE SYSTEMS

The ACA requires ACOs to demonstrate "a leadership and management structure that includes clinical and administrative systems." ACOs will need to detail for CMS not only its structure and governance, but also how it can make changes that will positively affect care. This portion of the application could also establish whether the providers within the ACO are clinically integrated for antitrust purposes. ACOs would detail what efforts they have underway to reduce costs and improve quality, such as capital investments to drive efficiencies, robust physician credentialing processes and programs to monitor and promote wellness. Below, we provide examples of programs Premier member hospitals have implemented as part of their journey to accountable care. **ACOs should, as part of their applications, provide examples to demonstrate "clinical systems" capacity to transform care.**

DATA AND HEALTH INFORMATION TECHNOLOGY

The ACA requires that ACOs "submit data in a form and manner specified by the Secretary on measures the Secretary determines necessary for the ACO to report in order to evaluate quality of care furnished by the ACO." CMS will need to clearly lay out the details of the quality reporting requirement in its NPRM. Moreover, CMS will need to consider the data needs of the ACOs, and propose health information sharing in reverse of this requirement. **Timely data from CMS is crucial to the effective operations of ACOs.**

Timely and comprehensive data are necessary for predictive modeling, identifying high-risk patients for intervention, driving care coordination across care sites, monitoring spending and constructing a continuous feedback loop on performance. Data provide a road map for budgeting, staffing, investment in technologies and performance improvement techniques. While those ACOs that do not make use of health information technology (HIT) can capture and use data for such purposes, adoption of electronic health records (EHRs), e-prescribing, teleradiology and other technology certainly facilitate such efforts. These systems allow the efficient collection of data, compilation of data into useful statistics on performance, transmission to others for benchmarking, creation of evidenced-based guidelines and integration of protocols into standard practice. **As such, CMS' initial contracting should give preference to organizations that are IT-enabled.**

Accepting Quality Data

Under the Physician Group Practice (PGP) demonstration, a CMS contractor developed an infrastructure to accept data, ensure security of the information and disseminate post-analysis reports. It is unclear how CMS will achieve this function within the national ACO program. Since many of the measures are expected to be beyond the existing Hospital Inpatient Quality Reporting Program (HIQRP), formerly known as RHQDAPU, and the Physician Quality

Reporting Initiative (PQRI) programs, CMS will need to build this capacity or contract with an outside organization to accomplish this. CMS is actively working on accepting data from EHRs as part of the Meaningful Use (MU) bonus program that is separate from the existing QualityNet system, but is not able to do so at this time. **CMS should detail its preliminary plans for the development and testing of an infrastructure to accept data outside the claims process for ACOs in its NPRM.**

Disseminating Quality and Efficiency Data

As noted previously, the success of ACOs depends on the receipt of timely and comprehensive data. The ACO's own data will not be sufficient for the required activities. Because ACOs are taking responsibility for an entire population, it is critical to know what, if any, services the beneficiaries are receiving outside of the ACO provider network. This can only be done if CMS provides data across the continuum to the ACOs. This information will not only be needed for ongoing operations, but also in advance of a CMS contract to determine if a certain ACO model is appropriate. **CMS must commit resources to ensuring that data across Medicare Parts A and B are shared with ACOs on a timely basis.**

Pharmacy data are also instrumental to the success on an ACO to both improve quality and reduce costs. For example, pharmacy data can be used:

- to identify high-risk cases (e.g., diabetics on insulin);
- monitor medication compliance (e.g., filling scripts on the right schedule);
- check appropriate use of medications (e.g., poly-pharmacy interactions); and
- identify beneficiaries who will hit the "donut hole" in coverage (risking non-compliance).

We recognize that under Medicare this data is generated as part of the Part D program, which is technically not part of the overall spending calculation within this program. However, it is vital information for providing high-quality care to beneficiaries. **We urge CMS to make strides to break down its own silos to ensure that prescription drug information is made routinely available to ACOs for their assigned population.**

Much needs to be worked out in terms of the form and timing, as well as transmission, of the data from CMS to the ACOs. In the private sector, our collaborative members are actively working with plans and employers to share data on a monthly basis in both directions. In some cases this is a large raw dataset, while in others it is dashboard reports containing calculated metrics. As we continue to work with private payors, we will provide information to CMS on what is considered appropriate on both sides. At minimum, ACOs will need baseline data for three years prior to the start of the program, and then ongoing information like demographics, risk scores, key quality indicators and overall spending. To the extent possible, some consensus across the public and private sector on quality metrics, as well as the content, form and timing of

data reports, would streamline ACO efforts. **We urge CMS to conduct a special listening session specifically on data needs, to include private payors who are already working with ACOs on these issues.**

In Attachment II we supply an example of the clinical and financial indicators we routinely report to our QUEST collaborative members around inpatient services. While we are still working to develop broader scope reports specific to the ACO Implementation Collaborative, we believe our example will provide CMS a sense of what ACOs will need on a regular basis. These reports allow hospitals to track their performance across time and against peer groups in a way that is easy to understand and act upon. Although quality metrics will be available on different schedules, utilization and payment data should be available monthly. **While we do not expect that CMS has the resources or capacity at this time to provide such reports to the ACOs, CMS will need to transmit the underlying data on the services provided outside the ACO on a regular basis.**

In Attachment III we supply an example of our practitioner profiles, which currently contain only professional services related to the inpatient stay. However, we will expand the data sets as our members enter into agreements with private payors and form additional relationships with post-acute care providers. These reports allow physicians and other practitioners to compare their performance against their peers within the same facility in the same specialty, all physicians within the facility, physicians within their specialty at similar hospitals and all physicians within similar facilities. In Attachment IV we provide a list of physician metrics that we are considering that would be appropriate for profiles furnished to physicians in the context of an ACO model. **Again, it would not be expected that CMS would provide such reports, but rather supply individual ACOs with the data elements needed to make such calculations by physician on a regular basis.**

Note that we do not expect or support sharing this level of physician data transparently with beneficiaries. The quality, utilization and spending measures would be provided to the ACOs to both encourage physician practice change and calculate the distribution of rewards to physician. Not all of these metrics are appropriate for ranking physicians or for public display.

In many cases, ACOs will contract with other entities, such as Premier, to process, analyze and develop reports from their data. If the ACOs receive the data and then in turn transmit it to the vendor, precious time will be wasted making the data reports actionable. **We urge CMS to allow ACOs to designate a vendor to receive the data from CMS on their behalf.**

Availability of Large-scale Datasets

CMS should also make large data sets more easily available to researchers and others to support the ACO program. Organizations like Premier routinely purchase the MedPAR file for the

preparation of annual comment letters under the FFS program, but it is more expensive and time consuming to obtain files that cross both Part A and B and these files do not include Part D data. Making linked datasets, even with de-identification precautions applied, would not only support more informed comments on the construction of the program, but would enable researchers to develop evidenced-based care bundles, risk adjustment models, etc. that would further advance the program. **CMS should, as part of the administration's Open Government Initiative, make robust linked data sets more easily available through a data user agreement process.**

It is unclear how section 10332 of the ACA may interact with the ACO program. This provision of the law requires the Secretary to make Medicare Parts A, B and D data available to "qualified entities" at cost. However, it is unclear if the data sets can be used for purposes beyond creating quality and efficiency performance reports, such as developing evidence-based guidelines. It also requires that such reports be made available to the public. While some of the metrics used for quality improvement within an ACO may be appropriate for public display, others may not have the requisite specificity and sensitivity for comparison across hospitals, or may not be intuitive for the average consumer. **We urge CMS to include a discussion in the NPRM about the availability of large-scale datasets and any constraints of their use.**

VALUE METRICS

The ACA requires the Department of Health and Human Services (HHS) to develop a national strategy to improve healthcare quality by January 1, 2011, through a transparent and collaborative process. The Report to Congress must include a comprehensive strategic plan that ensures the priorities identified will have the greatest potential to improve health, identify areas with potential for rapid improvement in quality, as well as address gaps in quality, efficiency and comparative effectiveness information. We are hopeful that the report will provide a cohesive, comprehensive long-term plan for the HIQRP, PQRI and MU programs as well as new delivery system reforms like ACOs.

CMS must in turn clearly describe in its NPRM how ACO measurement will interact with the HIQRP, PQRI and MU programs. It will be very difficult for providers to meet disparate requirements across these programs, all of which have payment implications. **CMS should structure the ACO reporting requirement to satisfy the HIQRP, PQRI and MU programs at the same time.**

Specifically, the HHS report and CMS rulemaking should consider the ACA language that requires ACOs to meet certain quality thresholds:

- Clinical processes and outcomes,
- Patient and caregiver perspectives on care and
- Utilization and costs.

We believe that measurement is central to determining the success of the ACO program and monitoring for unintended consequences. However, agreeing to the definition of "value" is the difficult first step in the measurement process. The Premier ACO initiative is basing the definition of value on simultaneously optimizing three areas:

1. **Population health status** — The health of individuals within a population and outcomes of care. This could be as broad as the mortality rate of a defined population, or more narrowly, the percentage of diabetics whose blood sugars are well-controlled.
2. **The care experience** —Satisfaction with the care experience, the level of personal engagement in self care and the extent to which people in the ACO actively work toward optimal health outcomes.
3. **Total cost of care** — The efficiency of the care system in delivering the two preceding outcomes. Typically this is measured as a total Per Member Per Month (PMPM) cost of care.

Measures are needed across each of these three dimensions to fully assess ACOs and their impact on patients. However, we do not have many outcomes-based, population-level measures across the continuum (including post-acute care, long-term care and hospice) available to us at this time. Moreover, many of the existing measures rely on the labor-intensive process of manually-abstracting data from medical charts. **HHS should make it a priority to identify gaps and develop broad-based measures, including electronic specifications, which can be applied on a population basis, in its national strategy.**

Phases

Due to the current lack of comprehensive measures, the ability of providers to efficiently collect data and the ability of CMS and other federal agencies to receive such information, the ACO program should phase in the measurement component of the ACO program. The Premier alliance recommends that CMS follow a four-phase process.

1. Out of necessity, to begin the ACO program by 2012, CMS will have to first rely on existing measures that have standard definitions and are in common use. These measures will largely rely on claims data, but will include other sources such as surveys of peoples' experience of care.
2. CMS should then add measures that rely on "clinically-enhanced" data, such as the inclusion of laboratory and pharmaceutical information.
3. Next, CMS should directly accept data from electronic health record systems that enables measurement at an individual level across the continuum.
4. Finally, true outcomes-based measures of population health, such as smoking and obesity rates in a community, should be integrated into the system.

Below we provide a framework for CMS to assess process, prioritize and implement measures in the ACO program based on the evolving landscape.

Framework

1. Selection of measures for the ACO program should be transparent and included in rulemaking to allow all interested parties an opportunity to comment.
2. CMS should undertake analyses and share them with the public, identifying areas in which it believes measures should be developed.
3. Measures may be developed by various organizations across the country from academic institutions to health plans, but need to be developed with automation in mind and use data elements that exist in EHRs today.
4. While it is generally preferred to use measures that have gone through the National Quality Forum's (NQF) consensus building process, other measures that have been widely used or tested in demonstration programs would also be appropriate for this stage.
5. Field testing should be conducted to validate the measures for accuracy, precision, sensitivity, specificity, efficacy, collection burden and unintended consequences to quality of care. The unintended consequences of the measure should be evaluated with regard to effectiveness, safety, timeliness and automation.
6. If field testing identifies flaws in the measures that suggest material changes should be made, the measures should be reconsidered by NQF.
7. CMS should consult with other federal agencies such as the Centers for Disease Control and Prevention and the Agency for Healthcare Research and Quality, given their experience with developing definitions, testing, data collection, healthcare-associated infection reporting and research.
8. In the ACO rulemaking, CMS should include the measures that it is specifically recommending for the first round of 3-year contracts. Before changing these measures, CMS should go through rulemaking similarly to the HIQRP program with plenty of advance warning.
9. CMS should consider coordination with measure sets used in the private sector, to the extent possible, to reduce the burden on ACOs.
10. In the rule, CMS should provide the public with information on:
    - the measures,
    - the risk adjustment methodology,
    - who developed each measure,

- which organization suggested the measure for CMS adoption,
- whether the NQF is actively considering the measure or has endorsed it,
- whether other consensus bodies such as the Hospital Quality Alliance are actively considering or have endorsed the measure,
- which organizations have field tested the measure,
- the results of the field tests,
- where related evidence-based practice guidelines can be found,
- detailed measure specifications and
- a plan for automating the measure if it is not already electronically specified.

11. CMS should consider staggering the adoption of measures to ease the burden on providers with at least one year notice of new measures before adoption.
12. CMS should take care to choose a reasonable number of measures that are not overwhelming in the early years.
13. CMS should endorse only measures where the exact specifications and methodologies for calculation are completely public, replicable and can be automated.
14. Focus should be placed on measures that have been shown to make a difference in the quality of care provided through research, and accurately assess whether evidence-based care has been delivered.
15. The ACO measure set should be structured to satisfy the HIQRP and MU requirements.
16. Data specifications for proposed measures should be posted on the website (if not QualityNet, CMS should specify where) when the NPRM is published.
17. Subsequent changes to data specifications should be posted to the CMS website (if not QualityNet CMS should specify where) and notices should go to providers through the QualityNet.org e-mail list notification.
18. CMS should seek comments on the retirement of measures through rulemaking. Retirement should occur when the standard of care has changed, when performance of the preponderance of hospitals is at or very near perfect or when an outcome measure is integrated that can take the place of a process measures (e.g., urinary tract infection rates versus catheter removal timing).
19. Once the measures have been endorsed, field tested and publicly reported, CMS may consider integrating the measures into the ACO reporting requirements.

Premier has preliminarily developed a core set of measures that we expect to use in the first phase of our Implementation Collaborative with the private sector. In Attachment V we provide

the measure name, the description, the measure developer and the data source. These are standardly defined and widely used measures. CMS may consider developing a core set of measures where required, but additional measures can be selected by the ACO based on the services they provide or already collect for another payor. **We urge CMS to consider these measures for the first round of three-year contracts under the ACO program.**

PAYMENT

The ACA gives CMS the authority to allow different payment models within the ACO program. We urge CMS to take advantage of this, as each ACO is at a different stage of readiness. In some areas, particularly where managed care is prevalent, ACOs are prepared to accept risk, including partial and full capitation. These organizations will not want to take a perceived "step back" to participate in a fee-for-service (FFS)-based shared savings model. **CMS should include at least a FFS and a capitation model in the program from the start.**

General Models

While there are numerous variants on these themes, we have described a few of the basic models for which CMS should consider accepting applications in the ACO program. We also provide additional detail on a few of the models for CMS consideration.

FFS+Bonus

Under this model, ACOs would continue to be paid FFS throughout the year for all services, and then receive a bonus at the end of a year if spending is lower than a benchmark plus a statistical confidence interval (CI) and if certain quality thresholds are met. Initially, there would be no down-side risk for the ACO if it were to exceed its spending target. However, over time, ACOs could accept symmetrical risk where the bonuses and losses are capped at the same levels and no CI is needed for statistical reliability.

Bundled Payments+Bonus

One payment (whether competitively bid or administratively determined) would be made for at least the hospital and physician services (and possibly post-acute care) provided during an episode of care. This could be a shorter period around a hospitalization or a longer period around a chronic condition. When setting payments for the bundles of care, if all evidenced-based care is included, the rates may exceed the current average FFS payment for those services. But, the expectation is that over time, this model will reduce overall spending. CMS would need to couple this model with a withhold mechanism or down-side risk to avoid higher payments than otherwise would have been paid. Moreover, this method of payment would not be applied to all Medicare services; some services would be paid on a FFS basis.

Global Capitation

Under comprehensive care payments, a single price would be paid for all services for persons cared for by the ACO for a period (likely a year), but adjustments to payments would be made based on health status and quality of care. The underlying payments would continue to be paid on a FFS basis (see discussion above), but at the end of the period a reconciliation against a total payment target would occur, with both an upside and a downside. A withhold would be necessary for this model to reduce the likelihood of overpayment, and thus would require retroactive recoupment. In addition, the withhold could be subject to quality targets in order for the ACO to fully earn it back.

Capitation

Another model would entail monthly, risk-adjusted capitated payments. These rates would be set based on projected spending, but adjusted monthly based on the risk scores of the currently attributed patients. The capitated amounts would be set well below projected FFS rates, guaranteeing savings for Medicare. However, if quality targets are met, ACOs would earn back the savings generated beyond the guaranteed savings. This could be applied as a partial capitation model where only physician services are capitated, and institutional claims are paid based on the FFS+Bonus method.

FFS+Bonus

Below we provide additional detail on how a FFS+Bonus model could be structured within the ACA parameters.

Beneficiary Attribution

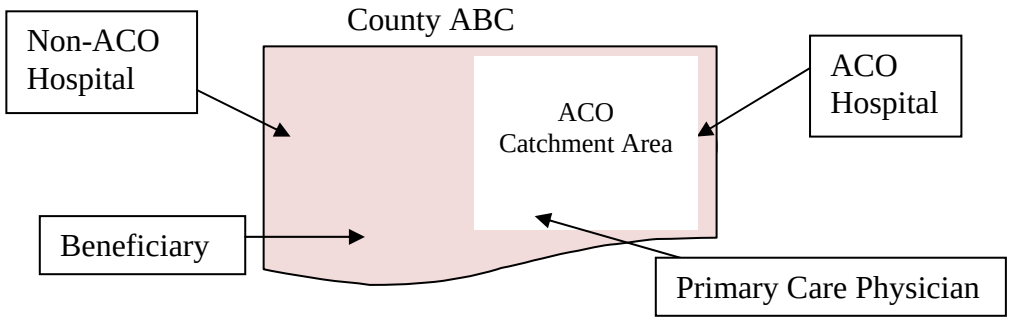
The population for which CMS will pay the ACO under the new program will have to be assigned through claims analyses, as required by the ACA. The original Physician Group Practice (PGP) demonstration, a precursor to the ACO program, matched beneficiaries to physicians by determining which primary care physicians or specialists were paid for the plurality of the beneficiaries' evaluation and management (E/M) visits.

Because enhanced primary care is central to the success of ACOs, it is critical that the beneficiary have a relationship with a primary care physician or physician extender. This connection should drive the inclusion of beneficiaries in particular ACOs. Specifically, CMS should determine if there was at least one visit with a primary care physician or ACO professional (general practice, internists, family medicine or geriatrician) in the prior year. If so, then the beneficiary should map to the ACO associated with that physician or ACO professional. If not, the beneficiary could be assigned to the specialist (limited to pulmonologists, cardiologist, rheumatologists, nephrologists, neurology, gastroenterology and endocrinologists) with at least two visits and the greatest allowable charges for services in the code range 99201-99215 in the outpatient department or physician office, but excluding emergency department services. While

this may result in matching fewer beneficiaries to an ACO, we believe this is the prudent way to begin the program. By relying on primary care services and a select group of specialties, there is a higher chance that ACOs will be able to predict in advance which patients will be assigned to them. Moreover, physicians who are not used as part of the assignment process can still be eligible for bonus payments based on their agreements with the ACO. **Thus, we recommend that beneficiaries first map to a primary care physician or ACO professional, and if not, based on the plurality of E/M codes to a subset of specialists. CMS should consider whether it is appropriate to match at the ACO or group level for ACOs that include employed physicians or physician group practices.**

CMS should develop a set of exclusions for certain beneficiaries. These would need to be agreed to in advance to prevent cherry picking. For example, "snow birds" should be removed, as the ACO will have no ability to affect the beneficiaries' health and care while at their alternate home or traveling. **CMS should propose a list of exclusions in its NPRM.**

Given the lack of a lock-in provision, CMS might also consider a geographic limitation in the beneficiary assignment process. Rural areas in particular draw from great distances. By limiting the distance from the components of the ACO that the beneficiary may reside, ACOs are more likely to be assigned beneficiaries who are able to seek other types of care from the ACO. Below we provide a simple example where assignment based on a primary care physician could result in a beneficiary who is more likely to use services outside the ACO. Within the Medicare Advantage program, there are limits on physician accessibility that may serve as a good model for a geographic limitation. Alternatively, ACOs could conduct analyses on their existing service area prior to the implementation of the ACO. **CMS should allow the ACO to include a geographic limitation in its application so long as rules are based on concrete criteria that do not involve risk selection.**



As stated earlier, we believe CMS should allow more than one ACO in an area. This will, however, require CMS to make a determination whether physicians can participate in more than one ACO. If so, this will complicate the attribution process. In some markets, forcing physicians

to choose an ACO will artificially restrain the development of the model. However, it is unclear if physicians would be able to actively participate in more than one ACO with differing care guidelines, focus populations, quality reporting, etc. **We urge CMS to watch private sector efforts like the Premier ACO Implementation Collaborative over time for additional insight on this issue.**

If CMS chooses to allow physicians to split beneficiaries between ACOs, we provide the following recommended model for attribution. Using the example above, the "Non-ACO hospital" could decide to form a partnership with area physicians and create its own ACO. In such a case, CMS could first match to the physician and then match to the hospital or other providers participating in the respective ACOs. If a patient only used physician services in the past year, CMS could look back two years. If the patient still had no other institutional claims, then the CMS should provisionally auto-assign the beneficiary, but allow him/her to actively choose the other ACO. This should be communicated by CMS as part of its beneficiary outreach plan described earlier. This would not lock in the beneficiary, but rather allow the ACO to contact the beneficiary to foster patient engagement. **If CMS allows physicians to participate in more than one ACO in an area, it should develop an additional algorithm, which includes institutional claims, to assign beneficiaries to an ACO.**

While ACOs by law need to agree to three-year contracts, we suggest that patient attribution occur annually during the payment reconciliation process for the FFS model (capitated model discussed later). With no lock-in mechanism, beneficiaries that do not receive the bulk of their primary care services within the ACO should not be assigned to the ACO. This can be achieved through a retroactive review of claims. To minimize the time lag, CMS should not wait more than 60 days after the close of the year or when CMS estimates 90 percent of the claims have been received, whichever is sooner.

While payment may be based on a retrospective review of claims to complete final assignment of beneficiaries, ACOs will need baseline information before entering into a contract with CMS to determine if a contract model is appropriate, as well as begin predictive modeling, determine provider network access needs and develop beneficiary engagement strategies. The first report should include three years worth of data to provide a historical view of the potentially-assigned population. This information also will be needed on an ongoing basis, as the population may shift in terms of age, clinical conditions, geographic concentration, dual eligibility, etc. This will assist ACOs in appropriately targeting services based on the needs of the specific population. **CMS should on a monthly basis provide lists of the beneficiaries that are provisionally assigned to them based on year-to-date information, as well as those excluded (due to opt-out, death etc.).**

Spending Calculations
The ACA requires CMS to measure the "estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Medicare Parts A and B services, adjusted for beneficiary characteristics." If actual spending is below projected spending minus a benchmark set by the Secretary (and potentially a CI), then the ACO is able to share in the savings.

Benchmark
The law directs CMS to establish benchmarks that are updated each year by the absolute growth in the national adjusted per capita spending across Medicare Parts A and B for the associated beneficiaries. Specifically, it notes that the benchmark should be adjusted by beneficiary characteristics, but also gives the Secretary latitude to make other appropriate adjustments. Below we suggest some adjustments CMS should make to the benchmark calculation. The ACOs will need this information to conduct financial modeling, plan operational changes and educate employees about the goal. **We urge CMS to establish the estimated benchmark 90 days prior to the beginning of the agreement period.**

Payment adjustments
While it is assumed that spending will be wage adjusted, the effects of other possible payment adjustments that may be made are unclear.. **Specifically, CMS should exclude disproportionate share hospital (DSH), indirect medical education (IME), direct graduate medical education, organ acquisition for transplants and bad debt payments from the calculation of spending and the associated targets.**

There has been significant volatility in the DSH factor recently due to changes in the data and methods used to calculate the adjustment. This instability will persist with the implementation of ACA payment reductions and will be unrelated to the effectiveness of ACOs operations. Including such payments in the calculation of spending will add variability that will be difficult to parse from true cost savings, and make it challenging for hospitals to predict risk, identify opportunity and gauge progress.

In either the case of add-ons or pass-throughs, efficiency gains will not affect the costs associated with these activities, and thus are not amenable to the objectives of the ACO model. For instance, better coordinated care may avoid a beneficiary needing a transplant, which would be captured in the savings calculations. But if a transplant is necessary, the organ acquisition costs will not change. In fact, teaching costs are likely to go up as reorienting teaching programs to a new way of thinking and practice will be resource intensive. In addition, if such costs are included in the national data used to set the targeted reductions, they may unduly influence the result. To arrive at an appropriate spending reduction target, CMS should look at the costs that are common to all hospitals for the services provided.

The reduction in hospital admissions under the ACO philosophy will result in lower add-on payments and distinctly disadvantage hospitals that provide substantial care to low-income patients and house residency programs. These payments, while paid on a per case basis, are in large part intended to reimburse hospitals for costs unrelated to the particular case. According to Mark McClellan, then Administrator of CMS:

> *The original intent of DSH payments was to reimburse hospitals for increases in their Medicare costs that were associated with treating a large share of low-income patients. Since that time, several changes to the statutory formula have increased the likelihood that DSH payments also compensate hospitals for the costs of treating uninsured patients.*[vii]

These obligations will remain even if Medicare admissions decrease. **CMS should consider including a policy to mitigate this disincentive for a key constituency of the program.**

Outlier payments are necessary even within the ACO construct. This prevents hospitals from avoiding particularly difficult cases and protects those that assume a disproportionate share of such cases. **We urge CMS to conduct analyses on FY 2009 data to identify what level of total beneficiary spending constitutes unusually high costs and consider using that as a cap.** The spending below this amount would be included in the calculations (national trend and hospital-specific trend), while the spending above it would not. This would prevent extraordinary cases from skewing the spending for a particular ACO and align incentives to ensure that difficult cases are not avoided. In analyzing the data, it may also become clear that certain services or conditions should be routinely removed, such as transplant surgeries or end-stage renal disease.

<u>Patient Adjustments</u>

Risk scoring

It is also expected that spending will be adjusted for age, sex, race and other indicators of clinical complexity. Given that a model already exists under the Medicare Advantage (MA) program, it is assumed that CMS will, at least preliminarily, rely on this method to determine and adjust for patient risk. Risk-adjustment is of paramount importance for the ACO program, as the enhanced benefits will inherently draw a higher-acuity patient population. **We urge CMS to further investigate risk adjustment methods that will capture more of the unexplained variation in spending and include additional variables such as socio-economic status.**

Normalization

We expect that CMS will normalize the risk scores, as is the case within the MA program, for the national trend. However, we do not believe that an offset to counter increased payments due to any improvements in documentation and coding that result in higher risk scores is appropriate for

the first round of ACO contracts. Because the bulk of these providers have not previously coded for such purposes, the first year or so of the program will not likely fully capture the severity of the patients. In addition, ACOs will not have the same ability to maximize coding accuracy as MA plans given the differences in the structures of the models. Moreover, a blanket adjustment will be inappropriate when ACOs have varied backgrounds in coding for risk score purposes. This would unfairly penalize certain ACOs. **CMS should not implement a coding offset. However, if it does, CMS should conduct analyses to determine if it is appropriate to apply different adjustments by region, ACO structure or payment model.**

Underlying Payment

Under the FFS+Bonus option, CMS will need to consider whether all the current and upcoming FFS payment policies will apply. For instance, under the Medicare inpatient prospective payment system (PPS), a national value-based purchasing program and a readmissions penalty will both begin in fiscal year (FY) 2013, while a hospital-acquired conditions policy will begin in FY 2015. Conceptually, we embrace tying payment to quality, as it is the foundation underpinning ACOs. Based on our current understanding of these policies, we believe they should apply to underlying ACO payment. These policies are consistent with the goals of an ACO and will further encourage improvements even if bonus payments under the ACO are not made. **CMS should apply quality-related payment policies to underlying FFS ACO payment.**

There are, however, other payment rules that run counter to the goals of an ACO. For example, post-acute care transfer policies reduce payments if the beneficiary is moved to certain other providers prior to reaching the geometric mean average length of stay for that diagnosis-related group. Also, under current policy, in order for Medicare patients to have skilled-nursing facility stays covered, they must first have a qualifying inpatient stay. Under the physician fee schedule, echocardiograms cannot be performed on the same day as a new patient visit, which is inconvenient and unnecessarily delays care. In Attachment VI, we provide examples of such policies that should not apply under the ACO model. Within an ACO, the goal is to treat the patient in the right setting regardless of payment policies that micromanage care and restrict innovation. As long as the ultimate outcome is high-quality, cost-effective care, the ACOs should be able to direct patients to the appropriate setting without reduced payment. ACOs will be mindful of care patterns that ultimately result in higher Medicare spending, as it will reduce the annual bonus and the quality measurement process will ensure that the quality of care is maintained. **Accordingly, CMS should not apply payment policies that penalize providers for directing the setting of care.**

Calculation of Shared Savings

CMS must determine whether ACO spending was less than the projected spending reduced by the national target and a CI to account for statistical variation. The spending reconciliation against the benchmark should occur annually.

Confidence Interval

Without a full data file, we cannot provide comments on the calculation of a statistical CI within which savings are believed to be a result of natural variation rather than true savings. We also note that such a window in which savings are not shared with the participants is not necessary for models that include symmetrical risk. **Thus, we urge CMS to not only release data files in conjunction with its rulemaking, but provide specific methodological detail around these calculations.**

Portion of Savings Shared Between ACOs and CMS

Even in a bonus-only model, ACOs will have to invest significant resources in order transform the delivery of care. Once CMS has established that the savings are not due to chance variation, and that actual costs are below the lower CI around the comparative target, the ACOs should be able to participate in all savings realized, not just the portion outside of the CI. This is particularly important for the smaller ACOs where the CI can be quite large. If first dollar savings are not allowed, these ACOs would have to far surpass savings realized by other ACOs in order to get the same reward. **Once an ACO demonstrates costs that are below the lower bound of the CI, then CMS should allow ACOs to share in first dollar savings.** The rationale is that once the comparative savings are judged sufficient to reject the null hypothesis of no savings (i.e., that actual adjusted costs are below the CI around the cost target and therefore statistically significant), then the most accurate measure of savings is the difference between the target and actual costs, not the difference between the lower CI and actual costs. Reducing the savings by the cost buffer would misrepresent true savings.

If CMS insists on including the CI in quantifying savings, then it could offset the bias described by varying the allocation of savings based on the size of the CI. For example, CMS could use a formula that allocated a larger share of the savings to ACOs with larger CIs to equate, for example, a 2 percent CI with 80 percent shared savings to the ACO. **In this manner CMS could vary the portion of the savings attributable to the ACO in direct proportion to the size of the CI.**

In any event, CMS should agree to generous rate-sharing in the first few years of the program. It will take significant funds for providers to transform their structures and processes to focus on value, and they should be compensated for this dramatic effort and risk. While this model does not explicitly include downside risk in the form or repaying Medicare if targets are exceeded, ACOs will still be investing substantial capital and human resources that have considerable opportunity costs. The cost of failure will be not only be felt in terms of money and resources expended to implement ACOs; adverse results could also include damage to physician and patient loyalty, loss of market share or other consequences. Moreover, without prospective lock-in of beneficiaries, ACOs will be providing enhanced services to *all* Medicare beneficiaries. Thus, the benefits will be felt far beyond the beneficiaries whose spending will be officially

measured as part of the program. **Premier suggests that CMS allow ACOs to share 70 to 80 percent of the savings in the first three-year contracts and then re-evaluate.**

Distribution of Shared Savings

It is important that CMS allow ACOs to grow into the program over time. Significant capital resources are needed to transform the system. Even those few organizations that participated in the PGP demonstration will need to continue to invest in their quality infrastructure to prepare for broader, more outcomes-oriented measures that will be developed for this program. At first, the improvements are likely to be a result of increased efficiency that then will diminish over time, while it will take longer to achieve quality gains that result in savings. Similarly to the PGP demonstration, a transition that splits the bonus pool into an efficiency payment and quality payment, with a heavier emphasis on quality over time, is appropriate. The goal should be to make 100 percent of the bonus contingent on quality scores over time. This may even be a transition that is specific to the time the ACO has been in the program rather than the program itself. For example, in the first 3-year contract, the pool could be split with 60 percent of the pool based solely on achievement of cost savings above the CI, while 40 percent could be contingent on meeting quality targets. In the second three-year contract 70 percent of the pool could be distributed based on achieving the quality targets, while in the third contract 100 percent could be based on the quality scores. **CMS should establish an efficiency pool and a quality pool with the quality portion weighted more heavily over time.**

Efficiency Pool

In order to obtain the efficiency pool, the ACO first would have to demonstrate savings above the target and the CI. As discussed above, if the CI is exceeded, then all of the savings should be shared at whatever rate is set by CMS (see "Portion of Savings Shared between ACOs and CMS" section). However, the ACO would also need to meet a minimum quality threshold to obtain the efficiency pool. This would be to ensure that the savings did not come at the expense of quality as measured by a subset of metrics such as mortality, readmissions and patient safety. This requirement would be a floor to ensure that there is no diminution in quality. **If this minimum quality threshold is met, CMS would distribute the entire efficiency pool to the ACO.**

Quality Pool

CMS would apply a composite quality score to the quality pool to determine which portion of the pool would be distributed back to the ACO. A scoring methodology would need to be developed based on the metrics included, resulting in more funds distributed to ACOs with higher quality scores. Generally, the scoring model should meet the following objectives:

- The scoring algorithm should incorporate process measures, outcomes, efficiency and patient experience, but not total spending, as that will already be captured.

- Scores need to be aggregated across clinical focus areas (where applicable) to an ACO-specific measure.
- The scoring methodology should allow for alternative weighting options across measures in the generation of the composite score for the ACO. For example, a graduated weighting scale could be implemented such that process measures are weighted more heavily in the first year, and less for each of the remaining years.
- The model should consider attainment and improvement in scoring, awarding the ACO the larger of the two, similar to what was proposed in the November 21, 2007, Report to Congress, as well as the recently enacted healthcare reform legislation.

Capitation

This model could be applied in whole or in part. For instance, ACOs could take capitated payments for just physician services or Part B, and then operate under the FFS+Bonus option for institutional care. CMS should not specify in advance the services that must be included in such a model, or require all services to be included. ACOs will need to assess, based on data analyses, which services have costs that can be accurately predicted and affected to the degree necessary to participate in this model. For instance, ACOs may choose to exclude services such as new vaccinations because the goal of vaccination programs is to promote higher, not lower use. In addition, there may be no previous vaccination cost data and prices can be unpredictably high based on supply issues. As another example, capitation may need to exclude outpatient infusion services that are very costly and vary based on patient needs. **CMS should allow the ACOs to designate the portion of services for which they are willing to take capitated payments.**

Attribution

Attribution under a capitated model would closely follow the process described in the FFS+Bonus section, but would need to be somewhat different as the assignment should be prospective rather than retrospective. CMS would first provide the ACO with a list of beneficiaries who would be assigned to the ACO based first on at least one E/M visit to a primary care physician or physician extender (family medicine, geriatrician or internist). If not, then the plurality of primary care services (but at least two visits) provided by the following medical specialists: pulmonologists, cardiologist, rheumatologists, nephrologists, neurology, gastroenterology and endocrinologists. In many cases, these physicians act as primary care physicians for certain complex beneficiaries, and should be included in the attribution methodology. This would be provided using 6, 12 and 24 months worth of the most recently available data. Risk scores would not be provided, as ACOs should not be selecting beneficiaries based on risk, but the data would include patient identifiers.

Next, the ACO would review the list and return a modified version to CMS restricting it to the beneficiaries who (based on objective criteria) use the ACOs services beyond primary care primarily or exclusively. This would assure that the ACO is assigned beneficiaries whose care it

can reasonably affect. Criteria could also exclude beneficiaries inappropriate for assignment to the ACO. To ensure that ACOs do not use this step to inappropriately avoid certain beneficiaries, selection criteria would need to be created in advance and approved by CMS. For example, the ACO could not disallow certain end-stage renal disease beneficiaries, but would have to remove them as a class. We would expect one criterion would be for conditions for which it can be difficult to predict expected costs, such as HIV positive beneficiaries where variance data could be used to demonstrate the necessity of the exclusion. Another criterion would be for beneficiaries who clearly receive services routinely in another geographic area that is not proximate to the ACOs location (also see FFS+Bonus section). Over time, the ACO may be able to reduce the applied exclusions as it gains experience under the model and is more confident in its ability to take on risk for a broader population. **The exclusion criteria should be specific to the ACO and determined in advance with CMS' approval.**

CMS would finalize the assignment after notifying the beneficiary, thus providing an opportunity to opt out (See "Beneficiary" section). CMS would then provide the ACOs with demographic data (including contact information), risk scores and baseline data on the usage of Medicare Parts A, B and D over the past three years. The ACOs will use these data in assessing patient risk and in planning engagement activities, staffing and budgeting, etc. **After the initial assignment process, beneficiaries would be added to the ACO's population based on a rolling 12-month's worth of data showing at least one primary care service or at least two E/M visits to the medical specialists listed above, but with the agreed-upon exclusions applied.** This assignment would take place every six months to reduce burden on CMS and provide the ACO more predictability. Refreshed data sets would also be provided at this time.

As discussed in the "FFS+Bonus" section, CMS will need a policy for physicians who want to participate in more than one ACO. Under a FFS model, we have suggested a possible method to assign beneficiaries and allow physicians to split their practice. **However, under the capitated model, where the ACO is taking on risk, we do not believe it is appropriate to allow physicians to participate in more than one ACO.**

<u>Capitated Rates</u>

CMS would use three years of historical data to project risk-adjusted expected payments for the attributed beneficiaries (see "FFS+Bonus" section on calculation of the projection), assuming no change in the underlying risk of the population, which would then be the basis for establishing a basic capitated amount to be paid on a per member per month (PMPM) basis. This would serve as an upper bound on rates to ensure that total spending ultimately would be less than otherwise would have been paid under Medicare, as required by the ACA. **Each ACO would then submit to CMS the base PMPM rate it would be willing to accept in each of the three years of the contract.**

This basic rate, however, would be multiplied by a risk score for each beneficiary to account for complexity and determine final payment. In addition, each month's PMPM payments would be reduced by the non-ACO services billed to Medicare in the prior month, starting with the second month of the program, unless the ACO took responsibility for the administration of such claims. ACOs would continue to bill under FFS rules so that CMS could calculate what it otherwise would have paid for the beneficiaries attributed to the ACO under FFS for research, future baseline calculations and investigation of possible unintended consequences. **The base rates would be adjusted for patient risk and reduced by non-ACO provider services.**

Quality targets

Unlike the FFS+Bonus model, there would not be a split efficiency and quality pool. Rather, rates would be set to achieve a certain level of savings, and annual quality improvement targets would be monitored over time. If a capitated ACO did not meet quality targets, then a penalty would be assessed. This would avoid the need for a quality withhold fund that would not be returned for more than a year. ACOs should submit the same quality data even if their underlying payment mechanism changes across contracts, or mixed models are utilized. **CMS should apply the same set of quality metrics to each payment model, and develop a payment penalty for capitated ACOs that are unable to meet quality targets.**

Spending Reconciliation

The ACA states that CMS can only accept capitated rates that it believes in any given year will result in lower spending than projected under FFS. However, it can set savings targets across the three-year contract. Thus, as long as expenditures do not exceed projected payments, an ACO could exceed their target in any given year, but then make up for it in another year. **Given that the ACO is at full risk for expenditures beyond the target, ACOs should be able to retain all of the savings beyond the guarantee unless quality targets are not met.**

Using an ACO that guarantees two percent savings off of the projected spending as an example, here are some annual reconciliation scenarios. The specific savings rates are meant to be illustrative. The policy would be structured to guard against a large overpayment requiring a one-time recoupment.

- Year 1
    - If the ACO was unable to achieve at least 1 percent savings in the first year, then the rates for year two would be reduced to reach that level.
    - If the ACO is able to achieve savings beyond 2 percent, the ACO would keep up to the 2 percent threshold and the remainder would be held in reserve by CMS in case the ACO does not meet its target in a later year.

- Year 2
  - If rates across both the first two years result in payments that do not achieve at least 1.5 percent savings, then either the reserve fund would be applied, if available, or rates in year three would be reduced to achieve this target.
- Year 3
  - If the ACO was unable to achieve at least 2 percent savings across the three years, then the remaining reserve fund would be applied, or the ACO would need to refund the spending above the guaranteed savings rate to CMS.
  - If the overpayment is minimal and the ACO signs a second three-year contract, the remaining funds could be offset from the following year's payments.

Capital Reserves

Under state licensure requirements, many ACOs need to maintain capital reserves to ensure stability and protect beneficiaries. We believe this is squarely in the jurisdiction of the states. ACOs should not have to meet two disparate sets of reserve requirements. However, we recognize that some states may not have laws and regulations governing risk contracts within healthcare that can be applied to ACOs, or may have policies that do not include capital reserves. In this case, it would be reasonable for CMS to create reserve requirements in the absence of state policy. **CMS should neither develop nor apply capital reserve requirements for ACOs operating in states that already have such laws and regulations.**

Stop Loss

Under the capitated model, ACOs are at full risk above total projected spending. However, CMS should be able to include a stop loss provision at a beneficiary level so long as the total spending target is not exceeded. Under the FFS+Bonus model, we suggest that CMS undertake data analyses to determine an outlier threshold above which beneficiary spending would be excluded from the projections and reconciliation process. Such a cap could be used to set a threshold above which CMS and the ACO would share in the losses, similar to the fixed loss threshold under the IPPS. This would create the appropriate incentives necessary to ensure that ACOs do not avoid extremely costly beneficiaries. **If annual beneficiary spending exceeded an empirically justified threshold, CMS will incur 80 percent of the loss, while the ACO would incur 20 percent.**

Coverage

A unique aspect of this model is that Medicare could allow the ACOs to provide otherwise uncovered services because the ACOs bear essentially full risk for outcomes and spending. So, for example, ACOs could provide home infusion services, dental services, adult daycare and custodial care if it believed that it would result in reduced total spending. Similar to Medicare Advantage, these items and services could be specified in advance in the contract with CMS, and could focus on wellness and prevention activities. **CMS should clarify that the provision of**

such additional services are not only allowed, but that the ACO could establish cost-sharing at its discretion for such services, or provide them for free (See Beneficiary Inducements section).

LEGAL ISSUES

There are a host of legal issues that arise with this new model of care and payment that need to be considered and clarified in order to remove impediments, whether real or perceived, that may delay the creation of ACOs. While we recognize that the Federal Trade Commission (FTC) and the Department of Justice (DOJ) have jurisdiction over antitrust law, it is our understanding that all the relevant agencies within the Administration are working in concert on this issue. We also acknowledge that the Department of Health and Human Service's Office of the Inspector General (OIG) plays a role in Anti-Kickback, Stark and Civil Monetary Penalties (CMP) enforcement. While CMS' focus will naturally be on the development of its own ACO program under Medicare as mandated by Section 3022 of ACA, we believe the market reality is that it may be difficult, if not impossible, to form an ACO for purposes of contracting to treat only Medicare beneficiaries.

The formation of an ACO requires substantial capital investment in enhanced primary care capabilities, interoperable electronic health records and other technology, as well as additional layers of management capabilities. In many communities, there may not be a sufficient business case to support these investments—by any of the providers—without the economies of scale that would flow from the ability of an ACO to contract with commercial payors as well as CMS. Providers' willingness to establish ACOs will therefore likely hinge on their comfort level that ACO contracting activities with *commercial payors* will survive scrutiny under antitrust laws.

We are hopeful that CMS can work with the various agencies to develop a coordinated approach, relying on the Secretary's statutory waiver authority and new guidance by FTC and DOJ, that would apply to contracting under the Medicare program as well as provide comfort to ACOs operating in the private sector. Alternatively, if CMS is unwilling to use its wavier authority, then the agencies should issue coordinated criteria for a comprehensive safe harbor and exception incorporating the points set forth below. Given that many organizations, including those in Premier's Implementation Collaborative, are moving with speed to be ready for CMS' ACO program, expediency is paramount.

Antitrust Issues

There are many examples of ACO-like organizations operating today, including many of the participants in the Premier ACO Collaboratives, as well as entities like MedSouth IPA, Greater Rochester IPA and Tri-State Health Partners, Inc., for which the FTC has issued Advisory Opinions. While these ACO-like organizations currently engage in joint contract negotiations

with commercial payors in conformance with existing FTC and DOJ guidance, there are certain areas and questions where additional guidance might alleviate industry concerns and foster more rapid, widespread and successful adoption of the ACO model as desired by Congress.

Clinical Integration

There exists significant overlap between the guidelines for clinical integration described in the Policy Statements, FTC advisory opinions and other industry guidance (e.g., Improving Health Care: A Dose of Competition and FTC Workshop: Clinical Integration in Health Care: A Check-Up) and the elements of clinical integration required to qualify for a Medicare ACO contract as outlined in ACA. Chart I below illustrates the comparison:

CHART I

ACA ACO REQUIREMENTS COMPARED TO CHARACTERISTICS OF PROVIDER NETWORKS WHOSE CLINICAL INTEGRATION PROGRAMS THE FTC HAS REVIEWED AND APPROVED IN ADVISORY OPINIONS

ACO Requirements	**MedSouth**	**GRIPA**	**Tri-State**
Accountable for quality, cost and overall care of patients	Yes	Yes	Yes
Formal legal structure that allows organization to receive and distribute payments	Yes	Yes	Yes
Includes sufficient number of primary care physicians for number of patients	Yes	Yes	Yes
Leadership and management structure that includes clinical and administrative systems	Yes	Yes	Yes
Reports on quality, utilization and clinical processes and outcomes	Yes	Yes	Yes
Defines processes to promote evidence-based medicine, reports on quality and cost measures, and coordinates care, such as through use of telehealth, remote patient monitoring, and other technologies	Yes	Yes	Yes
Meets patient-centeredness criteria specified by HHS	TBD	TBD	TBD

The FTC has considered other factors, as well, in its evaluation of clinical integration programs to achieve pro-competitive efficiencies that benefit patients/consumers as illustrated in Chart II.

CHART II			
ADDITIONAL FACTORS RELEVANT TO FTC ANALYSIS OF CLINICAL INTEGRATION PROGRAMS			
FACTOR	**MedSouth**	**GRIPA**	**Tri-Health**
Use of health information technology	Yes	Yes	Yes
Physician investment of capital	Yes	Yes	Yes
Non-exclusive contracting by physician members	Yes	Yes	Yes
Joint contracting ancillary to expected pro-competitive efficiencies	Yes	Yes	Yes
Enforcement mechanisms to ensure member compliance	Yes	Yes	Yes

Thus, any ACO that is awarded a Medicare ACO contract from CMS, pursuant to ACA, should be considered "clinically integrated" within the meaning of Policy Statements 8 and 9. Furthermore, we believe that joint negotiations and "sole-signature" contracting by the ACO are reasonably necessary to support the integrative goals of the ACO. Nevertheless, to alleviate any uncertainty among the provider community, **we ask the FTC and DOJ to confirm that any ACO that receives a Medicare ACO contract from CMS will be viewed as clinically integrated for antitrust purposes.**

Financial Integration

The Policy Statements contain several examples illustrating different forms of "financial integration" among competing providers that are sufficient to allow a provider network to jointly negotiate with payors under "sole-signature" authority without risk of violating Sherman Act Section 1 (or FTC Act Section 5). ACA provides that participating providers in ACOs may be eligible for incentive payments, including "payments for shared savings." This allows participating providers to receive a percent of the difference between the estimated average per capita Medicare expenditures in a year under the ACO and a benchmark established (subtracting a requisite confidence interval) by the Secretary if:

- The ACO meets quality performance standards established by the Secretary; and

- Estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries is at or below the benchmark set for the ACO by the Secretary.

The FTC and DOJ should provide guidance as to whether the "percentage of savings model" described in Section 1899(d)(2), as well as any other models the Secretary establishes, constitutes "substantial financial integration," as that is the term used in the Policy Statements.

Market Power

As Chairman Leibowitz has publicly stated, Medicare ACOs will not generally present market power concerns as long as the government purchases the services and unilaterally sets payment levels and terms—that is, as long as providers cannot negotiate prices with CMS. As stated previously, we believe that if Congress' intent to encourage proliferation of ACOs is to be achieved, it is imperative that providers receive adequate guidance from the FTC and DOJ concerning market power issues in the private sector. It is not yet clear how the FTC and DOJ will evaluate the formation and operation of ACOs contracting in private markets. The FTC and DOJ should clarify that ACOs contracting with commercial payors will be viewed like multi-provider networks as described in Policy Statement 8.

The Policy Statements do not articulate any antitrust safety zones for multi-provider networks because of the variety of arrangements found in the industry, and the constant evolution of new delivery models. However, we expect that in smaller, non-urban markets, providers may be reluctant to form or participate in ACOs out of a concern that the breadth of provider participation required to achieve meaningful care coordination will cause the ACO to be considered "overinclusive" for antitrust purposes. Particularly, specialty providers such as children's hospitals, tertiary or quaternary hospitals, critical access hospitals or "unique" specialist physicians may represent more than 30 percent of the applicable type of provider within the relevant geographic market, but inclusion of these providers will be necessary to truly provide accountability for all services provided to a population. These issues will be particularly acute in rural or other underserved areas. **We urge the FTC and DOJ to consider applying the antitrust safety zones articulated in Policy Statement 8 to each relevant provider component of multi-provider ACOs, and confirm that non-exclusive participation by certain specialty providers in an ACO will not create market power concerns. FTC and DOJ should also consider policies that will allow ACOs to be available in rural areas.**

Health Regulatory Issues

The formation and operation of ACOs directly implicates federal and state laws regulating the delivery and payment of healthcare services, including principally the Stark, Anti-Kickback and CMP laws (collectively, the Medicare Protective Laws). Given that the Medicare ACO program

mandated by the ACA will, at a minimum, involve a shared savings incentive that preserves FFS reimbursement for both Part A and Part B services, the Medicare Protective Laws will remain important tools to protect the interests of beneficiaries and the integrity of the Medicare program. Nonetheless, even federal enforcement authorities have recognized the need to re-think how the Medicare Protective Laws should be applied to ACOs.[viii]

At its core, the ACO concept reflected in Section 3022 of the ACA is premised on the perceived benefit to beneficiaries and to the Medicare program of encouraging a judicious reduction in medical interventions that are of questionable clinical value. Anyone who has been subjected to, or who has watched an ailing or fragile loved one endure, a prophylactic battery of invasive and often painful tests that yield marginally useful data can understand this point. Such overutilization, which is thought to be a major source of the runaway cost of healthcare in the United States, is the result of many factors, including profit-making pressures, fear of medical malpractice liability and ingrained patterns of practice. On the other hand, any payment system that creates incentives to lower the overall cost of services provided to patients runs the risk of encouraging stinting on care and adverse selection of patients by condition or payor source.

In light of the significant financial, organizational and cultural barriers faced by providers who would seek to form ACOs, it is imperative that CMS and other concerned agencies think and act boldly if they are to implement Congressional intent to foster the development of ACOs. In doing so, Premier believes that three significant points justify such boldness:

1. ACO participants will be required to submit all data that CMS and other regulators would need to determine whether fraud, abuse, stinting or adverse selection are occurring;
2. Each Medicare ACO contract will be for a finite, three-year term and presumably will be terminable by CMS for cause in the event that the data indicates that such fraud, abuse, stinting or adverse selection has occurred; and
3. Congress has granted the Secretary of Health and Human Services full authority to waive or modify the Medicare Protective Laws as necessary to promote Congress' intent.

In this sense the Medicare ACO program will be fundamentally different from the challenges CMS and the OIG have traditionally faced in regulating and enforcing the Medicare Protective Laws. In the past, the agencies appear to have been reluctant to grant broad safe harbors or exceptions, presumably in part out of the necessity of not exceeding their regulatory authority and in part due to the practical difficulty of policing abusive arrangements. We submit that in the case of the Medicare ACO program, the first of these concerns has been eliminated altogether, and the second has been significantly attenuated due to the self-reporting regime incorporated into Section 3022 of the ACA.

In many respect, ACOs are large-scale gainsharing arrangements. How the bonus funds are distributed within an ACO should be, to some extent, left to the ACO providers to determine.

The right mechanism for an ACO may differ based on the type, number and diversity of providers included. However, we recognize that CMS and the OIG will want assurances that beneficiaries and the integrity of the Medicare program are protected within these arrangements, and that the ACOs will want assurances that their structures do not violate the law. Below we propose a comprehensive safe harbor/exception for Medicare ACOs, and a suggested payment methodology. We are hopeful that CMS will recognize a number of payment models internal to the ACO within its ACO program, but at minimum, we recommend the proposal below.

Comprehensive ACO Safe Harbor/Exception

For a number of years, CMS has been considering a gainsharing exception to the Stark law, and the Premier alliance has twice submitted comments in this area. The OIG has undertaken a similar effort with respect to creation of a gainsharing safe harbor under the Anti-Kickback and CMP laws. We agree with CMS' statement in previous rulemaking that a "one-size fits all" approach to physician gainsharing will not accommodate all of the relevant stakeholders, and have encouraged CMS to create a broad gainsharing exception that allows hospitals and physicians to work together to improve the quality of care provided, while safely reducing costs. This concept is equally applicable to the shared saving program envisaged under Section 3022 of the ACA, since the use of financial incentives to achieve changes in practice patterns will be an essential tool within an ACO and central to its success and the future fiscal viability of the Medicare program.

In order to fall within a comprehensive safe harbor, we propose that ACOs provide a compensation plan to CMS as part of their application for a contract. This compensation plan would indicate the methodology, within the ACO, by which payments may be made by one ACO participant to another, and how any division of ACO shared savings bonuses or risk pools, among ACO participants, would be calculated during the term of the contract. If payments within the ACO during the term of the contract complied with the methodology set forth in the compensation plan, then the ACO would not violate the Medicare Protective Laws. The ACOs would have the burden of demonstrating, in the event of an investigation by enforcement authorities, that the ACO complied with the methodology described in the compensation plan. **CMS and the OIG should together establish a safe harbor and exception under which financial arrangements among participating ACO providers that comply with a compensation methodology plan submitted by the ACO to CMS would be deemed not to violate the Medicare Protective Laws.**

Premier encourages CMS and the OIG to set forth acceptable criteria for the design of such compensation plans, without being overly prescriptive as to form and approach. We believe that the most successful ACO incentive programs will contain a combination of incentive payments (payments for set improvements in quality) and shared savings (payments resulting from cost savings), as laid out by CMS in the Physician Fee Schedule final rule (Vol. 73, No. 224), November 18, 2008. We urge CMS and the OIG in establishing an ACO exception and safe

harbor to move beyond the product standardization gainsharing programs that have been approved to date in OIG Advisory Opinions that only achieve savings in the short run and are quality neutral. More comprehensive structures that will continue to build on quality improvement and cost savings opportunities over time and across the continuum of care will achieve the greatest positive result for beneficiaries and our healthcare system overall.

An example of a broader process improvement program, along with a possible compensation methodology, is set forth in Attachment VI. This illustrates what types of efforts should fall within such a safe harbor, as they will result in improved coordination of providers and quality of care. The compensation methodology is not meant to be the exclusive methodology, but one that CMS could approve for use by an ACO to provide certainty that they are not violating the Medicare Protective Laws.

Enhancing Access and Patient Compliance

To facilitate access to needed care and encourage beneficiaries' compliance with their treatment plans, ACOs should be able to provide incentives to those who need assistance. For example, one Premier member describes a disabled, low-income Medicare FFS beneficiary with uncontrolled diabetes who does not meet Medicaid eligibility, but also does not meet the hospital's charity care guidelines for a reduced hospital deductible. The patient cannot afford the relatively small co-pays (and transportation) to attend diabetes education or physician visits, but currently the health system is legally precluded from waiving copays or providing transportation for free. As a result, several times a year when the prescriptions run out, the patient lapses into a diabetic coma and arrives at the hospital emergency department via ambulance and is admitted to the inpatient setting for care.

ACOs have the potential to greatly improve care coordination and access to services, but in certain circumstances as described above, need the flexibility to use creative solutions to overcome barriers beneficiaries face in their homes and communities. ACOs should be allowed to offer items and/or services that promote better preventative care, chronic care management and generate increased participation by the beneficiary in the ACO. Such items or services could be free screenings or wellness services, co-pay and deductible waivers or transportation vouchers. In this regard, ACA provided an exception to the CMP law for remuneration that "promotes access to care and poses a low risk of harm to patient and federal health care programs," as designated by the Secretary under regulations. **We urge CMS and the OIG to include within the comprehensive ACO safe harbor/exception, or to issue separate regulations, that broadly permit the furnishing by ACO providers of free or discounted items and services to assigned beneficiaries that promote participation in and access to an ACO and/or medical home.**

Funding ACO Infrastructure Investments

In most cases, the formation of ACOs will require substantial capital investment in information technology and other systems, and additional layers of management, quality improvement and peer-review capabilities. Generally, not all providers participating in an ACO will have the ability to fund such investments. Similarly, in order to create the medical homes that lie at the heart of an ACO, it will be necessary to compensate physicians, physician extenders, nurses and other personnel for the considerable extra effort required to coordinate the care experience across the continuum.

Premier recognizes the long-held and valid concerns that CMS and the OIG have concerning the provision of free or discounted items and services to referral sources. The reality, nonetheless, is that unless hospitals and health systems are allowed to fund ACO infrastructure investments on behalf of those participants (primarily physicians) who cannot afford to underwrite such costs, only a relatively small number of highly-integrated delivery systems will be in a position to apply for Medicare ACO contracts. **We propose that ACO participants (Funders) should be permitted to support other ACO participants (Recipients) who may be in a position to refer Medicare business to the Funders through the coverage of infrastructure costs such as information technology acquisition and operation.**

While this issue has been addressed in the safe harbors and exceptions for programs that support the adoption of community-wide health information systems, electronic prescribing items and services, electronic health records as well as the recently issued "meaningful use" regulations, that guidance simply does not provide sufficient latitude to foster widespread ACO formation. For example, a Premier member reports that its offer to provide free electronic health record software to primary care physicians was rejected because the physicians could not afford to buy the requisite hardware – an expense that the hospital was not permitted to underwrite under existing guidance. Similarly, the requirement that physicians pay, upfront, 15 percent of a donor's costs to provide electronic health record items and services creates a significant (and in many cases insurmountable) barrier to establishment of the kind of data collection and reporting systems that an ACO must have in order to participate in the Medicare ACO program. Finally, it is not clear that ACO participants could qualify under CMS' and the OIG's existing programs, since it could be argued that provision of such items and services to ACO participants takes into account the value or volume of referrals or other business generated between the parties.

This is, however, assuming that overall referral patterns of such Recipients do not change materially in favor of the Funders, other than any shift in referrals attributable to beneficiary assignment under the Medicare ACO contract or participation by a Recipient in any managed care arrangement that requires referral to a Funder. **We urge CMS and the OIG to permit one or more ACO participants to fund infrastructure costs on behalf of other ACO participants, either through a broad exercise of its statutory waiver authority or as part of a comprehensive safe harbor/exception.**

Additional Guidance

In addition to the proposed safe harbor/exception, we urge the agencies to work together to provide as much guidance as practicable, whether that is in the form of advisory opinions, business reviews, preamble language, regulatory language or even FAQs. We hope that in this guidance you will confirm that there is no "one-size-fits-all" ACO model, ACOs need to be formed and operated based upon local market and competitive conditions and the law should accommodate such circumstances to achieve the broader goal of value in healthcare.

INTERACTION WITH OTHER PROGRAMS

The ACA specifically excludes ACOs from participating in other Medicare shared savings demonstration projects. **CMS should clearly state in its rulemaking the demonstrations already in existence or being developed based on legislative requirements in which the ACO program participants cannot participate.** ACOs need to weigh this in their considerations before submitting a contract application to CMS. Specifically, CMS should clarify whether ACOs can also participate in the medical home, bundling and gainsharing demonstrations. While a bundling pilot is explicitly required by the ACA, we believe the ACO program is separately authorized to include bundled payments as an underlying payment system. CMS should consider separately testing bundling within the ACO program to see if it results in greater savings than ACOs using standard FFS as the underlying payment mechanism, and/or bundling within the traditional FFS program.

MEDICAID ACOs

Section 2706 of the ACA authorizes states to create Medicaid Pediatric ACO demonstrations starting January 1, 2012. However, the statute is silent on the pathway to including Medicaid and/or safety net providers in the Medicare program. CMS should consider how Medicaid and safety net providers can contribute to the development of the Medicare Shared Savings program, as adult Medicaid beneficiaries and their providers present a unique set of challenges. Developing multi-payer ACOs, including Medicaid, early on is critical given dual eligible care costs and the substantial expansion of Medicaid – 10 million new enrollees are expected in 2019 and 16 million total in 2019. This will assist the Medicare program in determining how best to manage care and contain costs. **CMS should clearly delineate the interaction between the Medicare and Medicaid programs, and should prioritize the selection of multi-payer ACOs, particularly those with state Medicaid program participation.**

ACO-like Innovations Underway

State Medicaid programs and safety net providers are already experimenting to create coordinated networks of care, with the goal of improving care and reducing costs for Medicaid and the uninsured. A few of these initiatives include the following:

- In South Florida, three large public health care systems—the Public Health Trust of Miami-Dade County (Jackson Health System), Memorial Healthcare System (Hollywood, FL) and the North Broward Hospital District (Fort Lauderdale, FL)—formed the South Florida Community Care Network (SFCCN), a provider service network. The SFCCN facilitates provision of integrated care to Medicaid beneficiaries. Because the SFCCN aligns incentives among the three public healthcare systems, these systems are able to coordinate and manage the care process and improve efficiencies.
- Community Care of North Carolina is a medical home model that includes networks of community providers – physicians, hospitals, safety net providers, health departments and social service agencies. Community Care participates in the Medicare Section 646 Demonstration and, as a result, has expanded its focus to include dual eligible and Medicare beneficiaries, as well as Medicaid beneficiaries.
- Colorado intends to initiate an Accountable Care Collaborative and create Regional Care Coordination Organizations by early 2011. The state has requested comments on the program and RFPs are expected soon for a Statewide Data & Analytics Contractor and seven Regional Care Coordination Organizations (RCCO).
- California's Health Care Coverage Initiatives, which were created in 2007 as part of the current Medicaid waiver, have expanded healthcare coverage and provided medical homes to more than 100,000 people. All coverage initiatives participants are provided with medical homes for routine primary, preventive and chronic care.
- Finally, certain safety net providers that serve uninsured and Medicaid beneficiaries are looking to improve the financing of care networks. One example finds the Virginia Commonwealth University Health System partnering with the state to apply for waiver approval to use Medicaid disproportionate share hospital (DSH) funding to compensate primary care providers.

In addition to these activities, the reform statute allows states to initiate delivery system reforms in order to improve the Medicaid program – including experimentation with payment arrangements. One such initiative is the Medicaid Global Payment Demonstration (Section 2705). The demonstration is authorized in up to five states from 2010-2012 in order to move key safety net hospital systems from fee-for-service payments to a global capitated payment model. Parties interested in the demonstration are in the process of developing proposals (including Massachusetts). The CMS Innovation Center will evaluate this demonstration.

State Capacity

States must play a critical role in developing ACOs that include the Medicaid population. However, as state resources are considerably stretched, it is difficult to foresee that any states that have not already initiated this activity will begin doing so. As such, many multi-payer ACOs may not include Medicaid and an opportunity for Medicaid to be "on the cutting edge" of delivery system reform may be lost. This is tremendously important given that the success of the health reform statute in large measure rests on a successful Medicaid expansion and ensuring those beneficiaries have access to care. **As such, we encourage CMS to proactively invite comments on the role of Medicaid in multi-payer ACOs.**

Given the potential lack of capacity in many states to engage in the Medicaid reforms necessary to participate in a multi-payer ACOs, we urge CMS to provide guidance to states wishing to file waivers and/or initiate pediatric ACO demonstrations. This could take the form of technical assistance, template applications or convening all the state Medicaid directors for educational programs. CMS could also provide states with the basic specifications for the creation of ACO models that focus all, or in part, on dual eligible beneficiaries (in collaboration with the Center for Medicaid & State Operations and the newly created Federal Coordinated Health Care Office). **At minimum, CMS should immediately provide states with guidelines on establishing Medicaid ACO demonstrations. Ideally, CMS should structure the Medicare application process such that states could rely on Medicare ACO status to determine eligibility for Medicaid ACO programs, whether through a demonstration or a waiver.**

Safety Net Providers

Because safety net providers treat a patient population whose overall health may be more difficult to affect than others, CMS should give special consideration to ways in which it could encourage such providers to participate in the ACO programs, both Medicare and Medicaid. Specifically, CMS should consider socio-economic status as it develops policies around: risk adjustment, target setting, shared savings, underlying payment mechanisms, patient-centeredness criteria, quality performance standards and other reporting requirements. As an example, CMS should consider patient behavior patterns, including compliance with medical direction, literacy levels and availability of certain types of practitioners as part of its risk adjustment methodologies. **CMS should consider, and request public comment on, how safety net providers with high-volume Medicaid patient volumes can successfully participate in ACO models.**

PUBLIC DISCOURSE

We urge CMS to continue the public discourse around ACOs. While we have appreciated CMS' listening sessions, they have not provided many constituents the opportunity to comment, cover more difficult topics in depth or foster collaboration across public and private payors. As a new

program, we expect it to iterate over time based on lessons learned. Thus, additional venues for continued discussions across the healthcare field would be valuable to both the stakeholders and the evolving program.

In closing, Premier appreciates the opportunity to submit these comments on the ACO program. Please do not hesitate to contact Danielle Lloyd, senior director for reimbursement and policy analysis, at 202.879.8002 if you would like to discuss further.

Sincerely,

Blair Childs
Senior vice president, Public Affairs

cc: Ms. Nancy-Ann DeParle
Deputy Assistant to the President and
Director of Office of Health-Care Reform
The White House

Ms. Kathleen Sebelius
Secretary, Department of Health and Human Services

Mr. Daniel R. Levinson
U. S. Department of Health and Human Services
Office of the Inspector General

Mr. Eric H. Holder, Jr.
United States Attorney General
U.S. Department of Justice

Mr. Jon Leibowitz
Chairman, Federal Trade Commission

ATTACHMENTS REDACTED

[i] CMS National Health Expenditures at http://www.cms.gov/NationalHealthExpendData/.

[ii] Medicare Payment Advisory Commission. Chapter 2: Accountable Care Organizations. "Report to the Congress: Improving Incentives in the Medicare Program." 2009 Jun.

[iii] Shortell SM, Casalino LP. "Health Care Reform Requires Accountable Care Systems." JAMA. 2008 Jul 2;300(1):95-7.

[iv] Congressional Budget Office. "Option 37: Allow Physicians to Form Bonus-Eligible Organizations and Receive Performance-Based Payments." Budget Options, Volume I: Health Care. 2008 December.

[v] Table: Harold D. Miller, "How to Create Accountable Care Organizations," www.chqpr.com.

[vi] "A New Model of Care Delivery: Patient-Centered Medical Homes Enhance Primary Care Practices," www.ncqa.org.

[vii] Statement by Mark B. McClellan, MD, Ph.D., Administrator, Centers for Medicare and Medicaid Services on Tax
Exemption for Hospitals and Federal Payment for Uncompensated Care before the U.S. House of Representatives Committee on Ways and Means, Thursday, May 26, 2005.

[viii] Testimony of Lewis Morris before the Subcommittees on Health and Oversight of the House of Representatives Committee on Ways and Means (June 15, 2010).