June 6, 2011

Donald Berwick, MD, MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services

RE: Response to Medicare Shared Savings Program: Accountable Care Organizations (ACOs) Proposed Rule

Dear Dr. Berwick:

The 25 undersigned organizations are from a collaboration of leading consumer, labor, and employer organizations committed to improving quality and affordability of health care through the use of performance information to inform consumer choice, payment, and quality improvement. We appreciate the opportunity to comment on the Medicare Shared Savings Program: Accountable Care Organizations (ACOs) proposed rule.

Transformational programs are critical to addressing the quality and affordability crisis that Americans are experiencing with our health care system. The Patient Protection and Affordable Care Act (ACA) provides CMS with an unprecedented opportunity for creating these programs. We applaud the agency's leadership for seizing this opportunity with the Medicare Shared Savings Program: Accountable Care Organizations (ACOs). It sets a positive precedent for the implementation of the other new models of care in the Affordable Care Act.

We greatly appreciate the thought and effort CMS put into developing the proposed rule for ACOs. ACOs, if done "right," can be a tool that improves the quality and affordability of care. CMS struck the appropriate balance between encouraging participation and supporting the "*Triple Aim*" of better care, better health, and lower costs.

Admittedly, it would be difficult to develop ACO regulations that would make it possible for all organizations to participate. There has been public discussion that the proposed program will be difficult for providers that aspire to become ACOs. Less vocal, but noteworthy, are providers and health systems who are saying this program is well below their competencies. More importantly, though, we feel this discussion needs to be reframed. ***It is not about how many providers can participate; it is about making sure the program is designed to deliver better quality and more affordable care to consumers.*** Although some providers may not be able to meet all the requirements for shared savings, the proposed rule lays out the expectations of what constitutes an ACO if they decide to participate in the program in the future. Many organizations already claim to be ACOs, but we do not want to pay more for the status quo.

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Below, we provide comments on areas of the proposed rule that are particularly important to us. Following that is an Appendix that includes more detailed comments and recommendations.

- **Meaningful Quality and Cost Measurement and Public Reporting:** Performance measurement is integral to improving care delivery as well as evaluating success. CMS should seek to have a parsimonious core set of high-value measures for ACOs that evolves as better measures become available. The proposed set does a good job of addressing two parts of the *Triple Aim* - improving care and improving health – but does not adequately address the critical need to reduce costs. While meeting a cost benchmark will provide some insight into whether or not costs are reduced, it is not sufficient. Additionally, public reporting of measures should allow for transparency of individual provider performance. Public reporting is essential to reinforcing professional motivation for quality improvement and accountability, to guiding patient choice among ACOs and among physicians within ACOs, and to giving health plans and others information to guide contracting, tiering, benefit design, and pay-for-performance programs.

- **Payment that Drives Care Delivery Transformation:** Payment reform will not reach its full potential if it continues to be based on a system that is inherently flawed. CMS must improve the building blocks and mechanisms of current as well as future payment systems to ensure we have the right tools to monitor and manage cost growth and incentivize higher quality care. The Medicare Shared Savings Program is layered on a fee-for-service model that encourages volume and a fundamentally faulty Resource-Based Relative Value Scale (RBRVS). For these reasons, we believe CMS must move towards more sophisticated risk-based payment and improve the RBRVS. With that said, we still believe this program is appropriate for a specific group of providers that could reap financial benefits while improving care. We also look forward to additional ACO models being supported by CMS, such as the ACO Pioneer Program launched by the Center for Medicare and Medicaid Innovation.

- **Public-Private Sector Alignment:** As representatives of consumers and private purchasers of care, we see the devastating impact that uncontrolled health costs has on tens of millions of people in our organizations. Efficient care is a high priority to us, and the close alignment of private purchasing with public programs is absolutely essential to achieving this. Thus, designing ACOs with the private sector in mind is paramount to both the program's success and to achieving overall system transformation. In particular, CMS must ensure adequate protection against the adverse consequences of market dominance (e.g., increased prices for the private sector and cost-shifting) which contradicts the aim of reducing costs to the system. To address these concerns, we strongly recommend that the federal government monitor per capita costs and CMS require that ACOs include community representatives, especially consumers and purchasers, on their governing boards. Below we give other examples of how to provide protection and have sent recommendations to the Federal Trade Commission and Department of Justice in response to their Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program.

- **Significant Patient Engagement:** Patient engagement, patient-centeredness, and shared decision-making are foundational to creating a new care delivery system capable of achieving the *Triple Aim.* We recognize that, in practice, what works best for some of these elements are better developed than others, and thus CMS was appropriately more prescriptive in some areas than others. The agency should require evaluation of practices and use this as an opportunity to increase the knowledge base of what does and does not work in more nascent areas.

- **Balanced Participation in Governance:** The rule proposes inclusion of a Medicare beneficiary representative on the governing board and we strongly support broadening this proposal. We recommend including more patients, consumer advocates, employers, labor organizations, and other community organizations so there is proportional representation (i.e., 50 percent ACO participants, 50 percent other members) among the members of the ACO governing body.

On behalf of the millions of Americans represented by the undersigned organizations, thank you for your efforts to improve the quality and affordability of patient care. As you seek to transform Medicare, now more than ever, the changes made will have an impact on costs and quality in the private sector. We look forward to partnering with you on transforming the health care system. If you have any questions, please contact either of the Consumer-Purchaser Disclosure Project's co-chairs, William Kramer, Executive Director for National Health Policy for Pacific Business Group on Health or Debra Ness, President of the National Partnership for Women & Families.

Sincerely,

AFL-CIO
The Alliance
American Hospice Foundation
Buyers Health Care Action Group
Center for Medical Consumers
Catalyst for Payment Reform
Childbirth Connection
Citizen Advocacy Center
Consumers' CHECKBOOK/Center for the Study of Services
Employers Health Coalition of Ohio, Inc.
Employers Health Purchasing Corporation of Ohio
Florida Health Care Coalition
Health Care Incentives Improvement Institute
Health Policy Corporation of Iowa
Iowa Health Buyers Alliance
The Leapfrog Group
MidAtlantic Business Group on Health
National Business Coalition on Health
National Partnership for Women & Families
New Jersey Health Care Quality Institute
Northeast Business Group on Health
Pacific Business Group on Health
Puget Sound Health Alliance
PULSE of America
St. Louis Area Business Health Coalition

Appendix

The following are comments from a combined consumer, labor, and purchaser perspective on issues and questions raised in the Medicare Shared Savings Proposed Rule. We appreciate your receptiveness to our comments and look forward to providing further input when needed.

Eligibility and Governance

Eligible Entities Should Include Federally Qualified Health Centers and Rural Health Centers

In the Affordable Care Act and proposed rule, ACOs are defined as a group of providers that have the legal structure to receive and distribute incentive payments to participating providers (ACO participants). The ACA specifies four groups that are eligible to form an ACO for the program: (1) ACO professionals (physicians or practitioners) in group practice arrangements; (2) networks of individual practices of ACO professionals; (3) partnership or joint ventures arrangements between hospitals and ACO professionals; and (4) hospitals employing ACO professionals. In addition, it grants the Secretary of Health and Human Services (HHS) discretion to allow other Medicare enrolled entities to form ACOs. The proposed rule exerts this discretion and recommends that Critical Access Hospitals be eligible to form an ACO, but it bars Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs) from doing so. Rather, it provides incentives for FQHCs and RHCs to be a provider participating in an ACO. Excluding these organizations has grave implications for the accessibility of ACOs to vulnerable populations. Of the nearly 19 million medically underserved patients served by federally qualified health centers nearly 1.4 million are Medicare beneficiaries. Many of these beneficiaries live with multiple chronic conditions and could significantly benefit from improved access to primary care services and better care coordination. We appreciate the gesture of offering financial incentives to include FQHCs and RHCs as ACO participating providers, as well as the technical issues with how Medicare pays these organizations, which impacts beneficiary assignment and determining expenditures. **However, FQHCs and RHCs should have the opportunity to form an ACO for the benefit of their patients and CMS should develop a solution.**

Caution Regarding Hospital Participation

Hospitals are eligible to form an ACO. Although hospitals are an important component in the continuum of patient care, we believe the goal of improving care coordination, quality and affordability is more likely to be achieved by ACOs that are led by physicians. We are also concerned hospital-led ACOs may lead to higher health care costs, given the growing evidence that several hospital systems have achieved enough market power to demand price increases far out-stripping inflation.[1,2] Moreover, we strongly support ACOs being built around innovative care systems built around primary care, not inpatient or specialty care. **Thus, we recommend CMS give preference to ACO professionals (physicians or practitioners) in selecting participants and require the majority of the ACO participants on the governing board represent primary care providers.** Additional comments on the composition of the governing board are provided below.

Composition of Governing Board

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[1] RA Berenson, PB Ginsburg, N Kemper. Unchecked Provider Clout In California Foreshadows Challenges To Health Reform. *Health Affairs*, 29, no.4 (2010):699-705; Feb 2010.

[2] CH Williams, WB Vogt, R Town. How has hospital consolidation affected the price and quality of hospital care? Princeton (NJ): Robert Wood Johnson Foundation; Feb 2006.

The law establishes that ACOs must have a mechanism for shared governance. CMS asks for comment on whether or not 75 percent control of the governing body held by ACO participants is an appropriate percentage. We believe it is not. Nor should the governing body be dominated by a single corporate entity. Rather, CMS should increase non-ACO participant representation, requiring a multi-stakeholder board that engages key community representatives. The rule proposes inclusion of a Medicare beneficiary representative on the governing board and we strongly support broadening this proposal. **Furthermore, we recommend including more patients, consumer advocates, employers, labor organizations, and other community organizations so there is proportional representation (i.e., 50 percent ACO participants, 50 percent other members) amongst the members of the ACO governing body.** Successful ACOs in the private sector have a more balanced governance structure. Support for meaningful participation should be provided to community representatives (e.g., mentorship, processes that facilitate their active participation, etc.). As part of the application process, CMS should require ACOs provide evidence that the governing body is diverse and includes key stakeholders in the community. Stakeholders selected to participate on the governing board must not have a conflict of interest with the ACO or have an immediate family member with conflict of interest with the ACO. CMS should provide guidance on what constitutes conflict of interest (e.g., those with a vested interest in the ACO, those who work or have worked as medical providers, etc.).

Required Reporting on Participating ACO Professionals

Pursuant to the proposed rules, entities applying to participate in the Shared Savings Program must provide Tax Identification Numbers (TINs) of the ACO and the ACO participating providers, along with a list of national provider identifiers (NPIs) associated with ACO providers/suppliers. In addition, the ACO would be required to maintain, update, and annually report to CMS the TINs of its ACO participants and the NPIs associated with the ACO providers/suppliers. We strongly support requiring ACOs to provide and maintain a current list of TINs and NPIs. Among other things, this is important for having provider-level transparency on quality and costs. Therefore, the need for NPIs – which identify providers at the individual level – is especially great. We provide elaboration on provider-level transparency later in these comments.

Processes To Promote Evidence-Based Medicine, Patient Engagement, Reporting on Cost and Quality, and Coordination of Care

We strongly support requiring ACOs to promote evidence-based medicine, patient engagement, reporting on cost and quality, and coordination of care. The combination of these practices is extremely important to achieving a more effective, efficient, and patient-centered health care system. We agree with the assertion that it is too early to identify the best way to promote some of these practices, thus making it prudent to not be too prescriptive. However, CMS can strengthen this provision by:

1. Requiring sufficient level of detail on processes and tools that will be utilized;
2. Requiring ACOs to evaluate the practices and make adjustments as necessary;
3. Including measures that assess the intended outcomes of these practices in the quality reporting requirement; and
4. Holding ACOs accountable for adhering to their stated plans.

In regard to patient engagement, ACOs should be required to help patients answer these four questions:

1. What type of care can I expect from an ACO?
2. What are my options for care and the differences among them?
3. How can I improve my chance of achieving the outcomes I prefer?
4. How can I use the health care system to improve my chance of achieving the outcomes I prefer?

In regard to care coordination, the proposed rule states that strategies employed by an ACO to optimize care coordination should not impede the ability of a beneficiary to seek care from providers not participating in the ACO or place any restrictions not legally required on the exchange of medical records with providers not part of the ACO. **We strongly support both of these provisions and believe that ACOs should promote a system where providers are "gateways" to coordinated, high quality care in order to make ACO-based care desirable for patients.**

Patient-Centeredness Criteria

One of the most important provisions of the proposed rule is the requirement that ACOs meet eight specific criteria to be considered "patient-centered." Achieving patient-centeredness is essential to the transformation of a better health care delivery system. It has been ten years since the Institute of Medicine identified patient-centeredness as one of the six aims for quality improvement, but this has yet to be realized.

CMS proposes a robust definition of patient-centeredness using the following criteria:

- Surveys of patient experience;
- Beneficiary representative on the governing board;
- Evaluation of patient population needs;
- Individualized care plans for high-risk patients;
- Electronic exchange of information to support care coordination;
- Shared decision-making;
- Beneficiary access to medical records; and
- Processes for measuring performance and improving care.

These are recognized practices for promoting patient-centeredness. We strongly support their inclusion and urge CMS to maintain all of them in the final rule. Because an ACO's ability to deliver patient-centered care is so critical to the success of the program and for improving the quality and efficiency of beneficiary care, we urge CMS to specify how it will monitor and enforce the requirements that ACOs develop and adhere to all of the patient-centered criteria outlined in the proposed rule.

In other sections of these comments, we discuss surveys of patient experience and beneficiary representation on the governing board.

Under the proposed rule, ACOs will be required to identify high-risk individuals and to develop individualized care plans for targeted populations. We support these provisions as a core element of effective care coordination but emphasize care plans should be mutually developed by providers and patients. Furthermore, CMS should clarify for whom these care plans will be available and/or required. For example, individualized care plans may be:

- Offered only for people with chronic conditions,
- Offered to every patient but only mandatory for chronic condition patients,
- Created for every patient in a practice, whether well or ill.

CMS should provide guidance on what should be in a care plan, which will vary depending on whether being offered to a well patient or an ill patient. For well patients, it should contain immunization recommendations, exercise and diet suggestions, and schedule appropriate screening exams. For ill patients, it should include much more comprehensive plans and strategies. In both cases, access to test results through a patient portal with appropriate explanations would be proper for both the patient and all authorized caregivers. We also applaud CMS' suggestion that care plans identify community resources; this may be especially valuable for chronic condition patients. **Keys to successfully integrating individualized plans into ACOs are mutual development by providers and patients; commitment by both to adhere to it; and communication and collaboration across the ACO care team, the patient, and his/her care support group.**

Electronic Care Plans

Meaningful use (MU) of electronic health records is headed in the direction of electronic care plans in stages two and three, and it will be a critical function for ACOs as they engage patients and families in their care and coordinate care across providers. The final rule should clarify both where and how this will be demonstrated (e.g. will ACOs have to provide documentation of their systems and processes in their applications?). **The final rule should also specifically require patient and family involvement in the development of the care plan, and it should require that ACOs can transmit care plans electronically to patients and across the care team.**

We strongly support the requirement that ACOs have processes in place for the exchange of summary care records and urge you to explicitly incorporate care plan information into the summary of care. ACOs need to move more quickly towards requiring the electronic exchange of summary and care plan records. To accomplish this, we recommend that ACO participants be required to use the Office of the National Coordinator's (ONC) Direct Project messaging capability or something comparable. The Direct Project, funded and run by the ONC has resulted in a set of standards, services and privacy and security policies that enable secure email between clinicians. ACO participants should use this or a comparable service (such as that created by AAFP and SureScripts) to transmit care plans and summaries. Increasing the number of providers who have the ability to communicate electronically will foster more robust care coordination and support the kind of improvements in efficiency that can translate into reduced costs by avoiding costly repeat tests, medical errors and other unnecessary or inappropriate services.

The criterion for written standards/processes in place for beneficiaries to access their medical records seems redundant with HIPAA and does not appear to advance the kind of real time access to health information that facilitates patient decision-making and coordination of care. ACOs need to move beyond the bare minimum HIPAA standards and consider access to

electronic information as key to patient engagement and high quality care. They should have standards/processes in place for beneficiaries to electronically access their health information in a way that is aligned with the "View/Download" criteria proposed for stage 2 MU. Consistent with MU, ACOs should be accountable for having at least 10% of their patients accessing their health information online.

Program Integrity and Requirements – Prohibition on Certain Required Referrals and Cost Shifting

ACOs will require infrastructure changes that will affect and hopefully benefit their entire patient population served, including Medicare, Medicaid, or commercially insured patients. At the same time, the implementation of Shared Savings Program's ACOs could potentially result in cost-shifting within Medicare and to other sectors, which is not intended by ACA. This concern must be addressed to ensure that the implementation of these ACOs does not result in harm to consumers in the form of increases in premiums or reductions in benefits.

To do so, there should be a system for ongoing monitoring of the potential consequences of increased market power (i.e., increased prices for the private sector and cost-shifting). We support the proposed rule requiring CMS to analyze patterns in use of health care services within and outside ACOs. The proposed rule, however, is not strong enough to measure progress towards the goal of reducing system-wide costs. **We think it is vitally important for CMS to add requirements to the ACO program to build a more robust monitoring system for costs.** We expect the Federal Trade Commission and Department of Justice will play a central role in this monitoring as well. In particular, CMS should:

1. Require all participating ACOs have a mechanism for assessing performance on private sector per capita costs by the second year of the program. An ACO itself does not necessarily have to have a mechanism in place, but could work with other stakeholders (e.g., using data from local purchasers or all-payer claims databases).
2. Gather data regarding current market shares, market entries and exits, and pricing trends for the ACOs. This information should be collected initially in the application process to establish a baseline, and then on an annual basis to monitor and report publicly on potentially adverse market impacts of ACOs.
3. Set expectations for resource stewardship and waste reduction, including public reporting of quality *and* cost metrics (e.g., cost to charge ratios, professional fee billing rates, prices for episodes for public and private payers, total costs for beneficiaries assigned to the ACO for public and private payers, etc.).
4. Specify a standardized set of measures for costs, with input from consumers, purchasers, and other stakeholders.
5. Hold ACOs in the Shared Savings Program to a maximum threshold of price increase with their commercial market clients.
6. Move to requiring ACOs take part in all-payer claims databases (APCD). The APCD is a database comprised of medical, pharmacy, and dental claims, and information from the member eligibility, provider, and product files encompassing fully-insured, self-insured, Medicare, and Medicaid data.

Assignment of Medicare Fee-for-Service Beneficiaries

Beneficiary Assignment

The rule proposes that Medicare beneficiaries be assigned to an ACO if they receive plurality of primary care services from a primary care doctor in the ACO, based on allowed charges. Assignment is retroactive for the purposes of determining shared savings, but alignment of patients with an ACO will be done prospectively so the ACO will know which beneficiaries make up the pool of patients that could be assigned. This acknowledges the importance of informing patients about their participation in an ACO as well as addressing the issue of how to deal with patients who leave the ACO for care over the course of a year. For this model to work well CMS must provide ACOs with timely information on eligible patients in the ACO to support care management of the population. Later in this letter, we provide comments on safeguarding against the avoidance of at-risk beneficiaries.

Assignment to Non-Physician Primary Care Providers

We support ACOs being built around a core of primary care providers. However, we are concerned that the proposed rule excludes patients being assigned to non-physician primary care providers, such as physician assistants and nurse practitioners. We believe this contradicts the intention of the Affordable Care Act, which defines ACO professionals as "physicians or practitioners." Medically underserved communities (both urban and rural) depend heavily on a full range of primary care professionals**. By proposing a rule that effectively excludes patients whose communities lack primary care physicians, CMS neglects a portion of the population that would benefit from coordinated care. Thus, we encourage CMS to expand its definition upon which assignment is based to include other primary care providers.**

Beneficiary Notification

When and how Medicare beneficiaries are notified about ACOs is essential to beneficiary participation. The rule states that ACOs will notify beneficiaries if they are receiving care from an ACO at the time a service is delivered. We believe this fails to give the beneficiary adequate time to make an informed decision about participation. Rather, ACOs should notify beneficiaries at the beginning of the year that they will become participants of the ACO. This could be done based on the data CMS will give ACOs about beneficiaries that would potentially be assigned to them. This does not preclude using other avenues for communicating that a physician is participating in an ACO model of care. On the contrary, we strongly support the other methods of communication mentioned in the proposed rule. Additionally, ACOs should encourage their physicians to discuss ACO participation with their patients and provide coaching on the best way to discuss the topic.

ACOs are required to post signs in provider offices/facilities about their participation in the Shared Savings Program. ACOs will also make standardized written information available to the Medicare FFS beneficiaries it serves**. We urge CMS to develop a patient-friendly model for a written notice that can be used by ACOs and providers that explains what patients can expect from the ACO and providers in its network, as well as the attributes that differentiate ACOs from the current fee-for-service model, including the benefits of improved care coordination, better patient experience and higher quality care.** These model notices should be developed based on research with patients and families and input from consumer groups. In addition,

beneficiaries must also be provided with information about their rights and responsibilities in an ACO, including the option to move outside the network.

If beneficiaries believe they are being "locked in" to a new system without their consent, they are likely to reject it, which will jeopardize the potential advantages that ACOs may bring to the health care system. **If we have learned anything from consumer reaction to managed care models in the 1990s, it is that many consumers do not want and will not tolerate "gatekeepers" in health care. Rather, they want their providers to be "gateways" to coordinated, high quality care**. If ACOs provide patient-centered care that is well-coordinated, and create regular opportunities to receive feedback from patients and families about their efforts, beneficiaries are likely to choose to receive care from the ACO.

Quality and Other Reporting Requirements

Proposed Measures to Assess the Quality of Care Furnished by an ACO

There has been much public discussion around the number of measures included in the proposed rule. We believe that this debate focuses on the wrong issue. **The focus should be on the value of the measures for improving care and informing consumers about the quality of care, rather than the absolute number of measures.** The whole point of being *accountable* is being transparent about performance and making the necessary changes to make sure patients receive the best care at the lowest possible cost. Also absent from the discussion is that more than a quarter of the measures in the proposed set can be collected from survey or claims data, both of which require minimal effort from providers.

We appreciate CMS putting forth a "dashboard" of measures to foster a comprehensive assessment of care across providers and settings. Having a robust dashboard is integral to improving care and evaluating success in meeting the *Triple Aim*. The dashboard addresses two parts of the *Triple Aim* - improving care and improving health – but does not address the critical need to reduce costs. While meeting a cost benchmark will provide some insight into whether or not costs are reduced, that is only one dimension of costs consumers and purchasers need. Equally important is an understanding of how cost reductions were achieved. We provide recommendations for how to address this in other sections of this letter.

CMS should aggressively seek to have a core set of high-value measures that evolves as better measures become available. In particular, we are very supportive of the following proposed measures in a core set:

- Clinician/Group CAHPS (Measures 1-6)
- Medicare Advantage CAHPS: Health Status/Functional Status (Measure 7)
- Risk-Standardized, All Condition Readmissions (Measure 8)
- Care Coordination/Transition measures (Measures 9-11)

Clinician/Group CAHPS

The requirement that ACOs conduct surveys of patients about their experience of care with their physicians is of great importance for ensuring that ACOs practice patient-centered medicine. **Patients are in the best position to provide information on how well physicians listen, explain diagnoses and treatment options, make themselves accessible, and perform in other ways that research has shown are essential for good diagnosis, patient follow through with treatment plan, care coordination, patient and family engagement, and other aspects of care that lead to the results the Shared Savings Program is intended to produce.** Moreover, patient experience is an excellent indicator of how well care is delivered and has a direct link to improved health outcomes. The survey is a priority for patients precisely because of the impact that the domains measured in experience surveys have on patients' ability to improve their own health. What follows are recommendations for implementing the Clinician/Group CAHPS survey.

The Clinician/Group CAHPS survey instrument should be administered by independent survey organizations using the core survey instrument and protocol developed by AHRQ and endorsed by NQF—possibly including supplementary questions focused more specifically on care coordination, shared decision-making, prevention, and meaningful use of IT as such questions are developed and validated over time. While an annual experience survey will be important for public reporting and quality improvement, ACOs should also solicit ongoing feedback from patients. Thus, CMS should also require ACOs describe a plan for gathering more frequent feedback from patients. This could include ongoing surveying or qualitative activities – like patient and family advisory councils, focus groups, walk-throughs, etc.

Medicare Advantage CAHPS: Health/Functional Status

Understanding the health and functional status of a patient is important to providing quality care. We strongly support CMS seeking to include health/functional status measures in the ACO measure set. We support the inclusion of Medicare Advantage CAHPS: Health/Function Status, which refers to the Health Outcomes Survey and includes the VR-12, a widely recognized and standardized health survey. Two issues we think important to address regarding health/functional status assessment are the target population and timing of administration. CMS should consider identifying the most appropriate populations for targeted use of the survey (e.g., chronic conditions, procedures-based) and when it makes sense to administer for monitoring outcomes (e.g., pre-surgery and post-surgery time intervals). Setting expectations for performance will also be important to address. For example, for older populations, the expectation may be maintaining functional status or decreasing the rate of decline. Incorporating longitudinal measures is an important tool for managing the care of a patient population.

Risk-Standardized, All Condition Readmissions

Hospital readmissions are a significant contributor to health care costs. Readmissions–measured within 30-days and 90-days of discharge–may result from poor patient education at discharge, lack of follow-up or premature discharge. Research indicates that lack of care coordination between hospitals and community providers is a significant contributor to readmissions. We strongly support including a risk-standardized, all condition readmission measure for within 30-days of discharge. The risk-standardization methodology utilized for the measure should not

remove most of the variation; otherwise, there will not be meaningful differences amongst providers.

Care Coordination/Transition measures

Coordinated care is an essential element to providing better quality, more affordable care. Good care coordination is particularly important for vulnerable older adults, who typically use the most health care services but have the poorest health outcomes. We strongly support CMS including care coordination/transition measures and making it one of the five measure domains.

Replacing/Removing Measures

Above, we identify measures from the proposed rule that should be included in a high-value core set. The value of a performance measures is determined in part by its meaningfulness, ability to support both quality improvement and accountability, and the resources needed for data collection. In the spirit of having a high-value core set for ACOs when the program is launched, we make these other recommendations:

- CMS should give preference to HEDIS measures, where there are measures that overlap with the HEDIS content (e.g., colorectal cancer screening). Doing so will reduce data collection burden on providers and promote synergies between the public and private sectors. Many HEDIS measures can be collected via claims data and these measures have a long history in both the commercially insured and Medicare Advantage population. We recognize there will need to be modifications to the specifications for the ACO population (e.g., enrollment versus visit-based assignment) but these are minor, especially in comparison to the benefits of using these measures.
- Remove Hypertension: Plan of Care (#59). This measure combines blood pressure control and plan of care into the same denominator. There is already a Hypertension: Blood Pressure Control in the measure set and ACOs are required to have individualized care plans for high risk patients, so this measure is redundant.
- Remove Blood Pressure Measurement for hypertensive patients (#32); there already is a Hypertension: Blood Pressure Control in the measure set. The latter measure is superior and recommended for use in Medicaid quality measurement.
- Reduce additional redundancies and overlap in measures (e.g., Tobacco Use Assessment and Tobacco Cessation Intervention, Diabetes Mellitus: Tobacco Non Use; Adult Weight Screening and Follow Up, Heart Failure: Weight Measurement).
- Replace the Depression Screening measure (#34) with the PHQ-9, a nine item scale that assists with diagnosis and severity scoring for depression. This is currently in use in private sector ACOs.
- Clarify measure #41, Diabetes Mellitus: High Blood Pressure Control. The description in the proposed rule indicates it is a percentage of patients in control while the NQF measure description indicates it is just recording of blood pressure. If it is the latter, do not include in the measure set.
- Remove Diabetes Mellitus: Foot Exam (#44). This measure adds less value than the Diabetes Composite.
- Remove Heart Failure: Weight Measurement (#47). This is a standard of care measure and should not be included in the core set.

Measures to Add to Future Core Set

We strongly support CMS' intention to focus on including measures of outcomes, functional status, and patient experience in future measure sets. We strongly recommend that CMS also consider focusing future measure sets on care coordination and efficiency as well.

Requirements for Quality Measures Data Submission by ACOs

The following are additional recommendations for improving the data and reporting requirements for ACOs.

- Reporting that allows for transparency of individual provider performance. Public reporting at the individual provider level, when feasible, should be a participation requirement for the Shared Savings program. Public reporting is essential to reinforcing professional motivation for quality improvement and accountability, to guiding patient choice among ACOs and among physicians within ACOs, and to giving health plans and others information to guide contracting, tiering, benefit design, and pay-for-performance programs. Thus, when using standardized surveys the methodology should be designed to produce reliable results at the individual physician level and for the results also to be aggregated to the ACO level. Similarly, we are concerned that setting a sample size of at least 411 patients for ACOs will not always foster reliable reporting on the individual clinicians within the group.

- Reliably reporting results. There will be instances where ACOs do not have enough patients to reliably report a measure. When this occurs, we recommend measures remain in the core set but not contribute to the quality performance standard (and the calculation for shared savings) and are required for internal quality improvement and reporting. We urge CMS to find other ways to deal with the "small numbers" issue, such as incorporating more composites in the core set.

- Longitudinal measurement of patient populations. Given that a primary purpose of the ACO model is to manage care for a population of patients, we strongly encourage CMS to include longitudinal measurement into the program, such as improving care or maintaining health status for chronic conditions.

- Inclusion of private payer data. ACOs will require infrastructure changes that will affect, and hopefully benefit, their entire patient population served including Medicare, Medicaid, or commercially insured patients. For Medicare-only ACOs in this program, CMS should consider allowing the use of commercially insured patients in the data for performance measurement. There is precedence for this in the Medicare Hospital Inpatient Quality Reporting Program and Medicare Hospital Value-based Purchasing. Not only does it promote alignment between public and private sectors, on a practical level it is one solution for the "small numbers" issue.

- Assessing and reducing disparities in care. We urge CMS and ACOs to examine performance measures by race, ethnicity, gender, preferred language and disability status and report these results. This will move ACOs forward in the drive to reduce and eliminate health disparities and also identify any areas where improvements are necessary.

- Alignment with other federal programs. We are extremely supportive of promoting consistency and creating a core set of high value measures that can be used in a variety of HHS initiatives. To facilitate rapid improvements in care and judicious use of public funds, it is extremely important these measures are high value and not include low value measures for the sake of alignment. There will be a need for multiple core sets based on type of provider (e.g., primary care providers, specialty care providers, hospitals, etc.).

Quality Performance Standards

Performance on each measure will be scored on a linear points scale. Domain scores are the average of the measures within that domain. The percentage of points earned for each domain will be aggregated using an equal weighting method to arrive at a single percentage that will be applied to the maximum sharing rate for which the ACO is eligible. We support measure scoring on a linear points' sliding scale as the program gets off the ground. We also support CMS' proposal to set the quality performance standards at a higher level in subsequent years.

While we support equal weighting of domains, we are concerned that measures in domains that do not have many measures will be more influential on the overall quality score. CMS should look to having a more even distribution of measures across the domains.

In determining the comparison ACO performance level, initially percentile, and not percent, should be the reference. Over time, though, standards for quality should be set at higher levels. Similarly, we support eventually using the ACO's own scores for calculating the benchmark.

For the first year, ACOs only have to collect and report the results to CMS. We encourage CMS to consider requiring the two-sided risk model to be based on performance in the first year for at least a portion of the measures in the core set. In subsequent years performance determines shared savings (or loss), in conjunction with cost.

Public Reporting

Public reporting is required for certain information regarding the operations of the ACO. This includes information on: 1) providers and suppliers participating in ACOs; 2) parties sharing in the governance; 3) shared savings distribution; and 4) quality performance standard scores.

We recommend CMS augment the information on shared savings by requiring ACOs to publicly report cost information. ACOs should publicly report Medicare total costs for beneficiaries assigned to the ACO and total costs for the commercially insured receiving care in the ACO. ACOs should also publicly disclose their episode prices for routine procedures (under the ACA Medicare is required to develop Medicare episodes for the public domain) for Medicare and an average price (blended fee schedules) for commercial payers. This information will provide insight on whether or not an ACO is meeting the savings targets by increasing prices in the commercial market.

The amount of transparency on quality performance in the proposed rule is minimal and problematic, especially if reporting is only at the ACO level. This moves us steps backwards from the individual provider and provider group reporting currently happening in public and private sectors**. Other provisions in the ACA require provider-level reporting and we think that was the intended spirit of the law for ACOs as well. Therefore, CMS must require both provider-level and ACO-level reporting.** It is not sufficient for measurement and reporting to

take place at the ACO-level only. Research has shown that much of the variation occurs at the individual provider level, not the practice site, group, or health system level. Knowing how an ACO scores is not sufficient to guide incentive programs that can motivate individual physicians. We have seen this for the Sustainable Growth Rate; reporting at an aggregate level does not motivate individual physicians to make changes. Moreover, for a program to be truly patient-centered, it must give consumers information at the individual provider level. To not do so is misleading given all the variation in quality that will be present in ACOs.

Improving Electronic Health Records Technology

We strongly support alignment between ACOs and Meaningful Use. ACOs are one of the key entities driving delivery system reforms and implementing many of the core functionalities expected of an ACO (e.g. comprehensive care coordination, meaningful patient engagement) is dependent on having a strong foundation of health IT and health information exchange. ACOs should be leading the pack when it comes to being meaningful users.

We support having 50 percent of eligible professionals be meaningful users of HIT as a core requirement for becoming an ACO. ACOs are not a simple tweak on today's system; the kind of patient-centered care they must deliver cannot be done well or consistently without health IT.

While we support this requirement, we also believe that specialists and hospitals are critical players in delivering coordinated, efficient and effective care. As an alternative to this requirement, CMS could examine the quality measures ACOs will report, and publish a list of the top 5-10 specialty types that contribute most to improving performance, including but not limited to primary care. CMS could then require 50 percent of these provider types to be meaningful users. We believe this would better facilitate building the infrastructure for care coordination.

For hospitals, we understand the challenges they face in becoming meaningful users, but we also understand the central role they play in reducing readmissions, ensuring smooth transitions, and coordinating with primary and specialty care to improve health outcomes. At a minimum, they should be required to deliver timely electronic discharge summaries to primary care physicians and/or the post-acute facility receiving the patient, and a copy of this information should also be provided to the patient and/or caregiver (in whatever medium they prefer – electronic or paper). This is consistent with meaningful use.

To do so, we encourage CMS to require hospitals to use The Direct Project standards, services and policies created by ONC. The Direct Project is essentially secure email that any clinician can use to send information and attachments such as care summaries, discharge instructions and care plans. While it can be integrated into an EHR, one is not required. Hospitals need only have an Internet connection to be able to use Direct or another comparable service that uses the Direct standards. According to ONC, any clinician can establish a "Direct Inbox" for free or purchase upgraded services at a very nominal cost.

In addition to all hospitals in the ACO using Direct or a comparable service, we believe that 25 percent of hospitals participating in the ACO should either be meaningful users, or be registered to become a meaningful user within one year. In ACOs with between one and three hospitals, at least two should be meaningful users or be registered for the program.

Shared Savings Determinations

Payment reform will not reach its full potential if it continues to be based on a system that is inherently flawed. CMS must improve the building blocks and mechanisms of current, as well as potentially future payment to ensure we have the right tools to monitor and manage cost growth and incentivize higher quality care. The Medicare Shared Savings Program is layered on a fee-for-service model that encourages volume and a fundamentally faulty Resource-Based Relative Value Scale (RBRVS). For these reasons, we believe CMS must move towards more sophisticated risk-based payment and improve the RBRVS. With that said, we still believe this program is appropriate for a specific group of providers that could reap financial benefits while improving care. We also look forward to additional ACO models being supported by CMS, such as the ACO Pioneer Program launched by the Center for Medicare and Medicaid Innovation.

CMS will evaluate ACOs' success by comparing their incurred costs to a benchmark comprised of patients who would have been assigned to the ACO in the three years prior to the agreement period. This comparison group actually reflects the ACO providers' cost in years prior to becoming an ACO. The comparison target will be updated by projected growth in national per capita expenditures as well as beneficiary characteristics. We are concerned that the costs do not include Medicare prescription drug coverage. This is a place where savings can be gamed by shifting costs from other parts of Medicare payment (e.g., use self-injectible biologics that are covered under Part D instead of comparable infused biologics covered under Part B).

ACOs can choose one of two payment models. The first one does not require the ACO take on any risk for the first two years if it loses money, but it holds the ACO accountable for losses in the third year. Organizations electing this model would be eligible for 50% of any savings it generates over a 2% threshold. The second model holds the ACO accountable for losses in each year, but it can receive up to 60% in shared savings over the 2% threshold. **We support giving ACOs the option of taking on more risk and getting a greater reward for doing so. We also support having a model that allows ACOs to ramp up capabilities before taking on risk and the risk element should remain intact in the final rule.**

Monitoring ACO Avoidance of At-Risk Beneficiaries

The crux of the Shared Savings Program is for ACOs to coordinate care for the sickest beneficiaries to improve their health outcomes while improving cost efficiency. Unfortunately, the same reason that makes the Shared Savings Program attractive also creates the potential of incentivizing ACOs to avoid the sicker and costlier patients. We support CMS's proposal to monitor ACOs for signs of intentional avoidance of high-risk patients as well as the plan to impose corrective action on an ACO found in violation of this principle. We also support termination of ACOs with particularly egregious behavior.

CMS is soliciting comments on whether lesser sanctions may be appropriate. We believe not. The standard used throughout the regulation is a combination of corrective action plan followed by termination if behavior has not changed. That standard should be maintained for the purpose of consistency. Furthermore, lesser sanctions may not be enough to prevent an ACO from engaging in patient selection.

Finally, we suggest CMS assess the construction of the expenditure benchmark and the impact it may have on unintentionally providing incentives to avoid at-risk beneficiaries.