

June 6, 2011

Dr. Don Berwick Administrator Centers for Medicare and Medicaid Services Room 445-G Hubert Humphrey Building 200 Independence Ave. SW Washington, DC. 20201

File Code: CMS-1345-P

Dear Dr. Berwick:

The Campaign for Better Care (CBC) appreciates the opportunity to comment on the Proposed Rule for the Medicare Shared Savings Program – ACOs published in the Federal Register, vol. 76, no. 67, pages 19528 to 19654.

The CBC is a broad-based coalition of consumer organizations - national, state, and community - with a direct stake in improving the health and guality of life for older adults with multiple health conditions and their family caregivers. We are committed to ensuring that new models of care delivery and payment, including Accountable Care Organizations (ACOs), provide the comprehensive, coordinated, patient- and familycentered care that individuals want and need while at the same time driving down costs.

The stakes are very high, and there is enormous pressure for our health care system to deliver on the promise of better outcomes and lower costs. ACOs could be a critical vehicle for this long-awaited transformation, and it is essential that CMS establish the right vision and direction for this program. Overall we believe you are moving in the right direction with the proposed rule, and we applaud your commitment to ensuring ACOs deliver truly patient-centered care.

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Changing the outcomes produced by our health care system requires genuine change in provider behavior and payment incentives, which will in turn drive patient outcomes, experience, and engagement. We know that true transformation of this magnitude is no small feat. It will require hard work by providers and payers. But we can no longer afford the status quo, either in financial or human terms. Patients and their families have long deserved better.

While some are concerned about asking too much of ACOs, we cannot expect genuine transformation to be easy, and we know that these new models must be held to standards that ensure they deliver on the promise of better care, better health, and lower cost. If the bar is set too low, ACOs will likely fail – either by failing to produce real results through a fundamentally different approach to care, or by creating resistance among patients who are called on to pay for or be part of mediocre attempts at change. We are very pleased that the guiding principles upon which the ACO proposed rule is premised include patient-centered care, patient engagement, a strong foundation of primary care, performance measurement including patient experience, and meaningful stakeholder involvement. These elements, we believe, are the key to a successful ACO program and genuine transformation of our care delivery system.

There are many provisions of the rule that are especially strong and we urge CMS to maintain them. We have also identified specific areas where we believe the rule needs to be strengthened. Our specific comments follow.

ACO Structure and Governance - §425.5(d)(8)(i)

The proposed rule requires that an ACO establish and maintain a governing body with adequate authority to execute the functions of the ACO. The rule proposes that a Medicare beneficiary representative be included on the governing board. The beneficiary must be someone who is served by the ACO, has no conflict of interest with the ACO, and has no immediate family member with a conflict of interest.

Beneficiary and Community-Based Representation

We believe an ACO governing board should be a multi-stakeholder body that operates in the public interest and reflects the community it serves as well those providing care. We commend CMS for requiring beneficiary representation on the ACO governing body but strongly recommend that there be a greater ratio of beneficiary representatives to practitioners. It is critical to ensure that the consumer voice is sufficiently represented to have an impact on the direction of the organization.

We agree with the proposed criteria Medicare beneficiaries must meet in order to be eligible. Too many times in the past we have seen consumer slots on boards and panels given to a practitioner or other expert simply because the representative met the age criteria. Beneficiary representatives to ACO governing bodies must truly represent the beneficiary population that receives Medicare services. We also recommend that CMS require the ACO governing body to include consumer advocates from *community-based consumer organizations*. Requiring both individual beneficiaries and community-based consumer advocates to hold a number of seats on the governing body will enable them to have meaningful *influence on the organization and its operations*.

We define individual beneficiaries and consumer advocates in the following way:

- Individual Beneficiary A beneficiary is an individual who has significant personal experience receiving services from the health care system. A beneficiary draws upon these experiences to help providers and practitioners better meet patient needs.
- Community-based Consumer Advocate Consumer advocates are individuals who work at nonprofit, mission oriented organizations that represent a specific constituency of consumers or patients. What distinguishes consumer advocates from other stakeholders is their primary focus on the needs and interests of patients/beneficiaries and family caregivers. They do not derive their livelihoods from the health care system as providers, health plans or employers do. They often are a trusted source of information in the community. They have experience representing the diverse needs and perspectives of different types of beneficiary populations. They are skilled at working with diverse stakeholders, understanding different perspectives, and forging solutions that address a range of interests and perspectives.

Representation Threshold

CMS asks for comment on whether more or less than 75 percent control of the governing body being held by the ACO participants (physicians) is an appropriate percentage. We support lowering this percentage to 50 percent. We also suggest that CMS require that 50 percent of the seats on the governing body be held by beneficiaries, community-based consumer advocates and other relevant stakeholders – who are committed to the goals of the ACO but do not derive livelihood from the ACO or one of its providers.

Demonstrating Beneficiary and Community-Based Consumer Participation

Consistent with the requirement in the proposed rule that an ACO provide evidence that the governing body includes ACO participants, we urge CMS to require ACOs to also provide evidence that the governing body includes beneficiary and consumer advocate representation. If ACOs claim that state laws prevent beneficiaries and consumer advocates from participating on governing bodies the ACO must provide ample supporting documentation and request from CMS an exemption from this requirement.

We support CMS' proposal that ACOs explain in their applications how they will integrate community-based organizations and urge CMS to provide more guidance on what it means to partner with these resources.

We do not agree with the proposal that including a community stakeholder on the governing body will deem an ACO as having met the requirement of partnering with community-based organizations. Having community stakeholders on the governing body does not take the place of actual partnership with community-based groups.

Beneficiary Alignment - §425.6

The rule proposes that Medicare beneficiaries are aligned with a particular ACO if they receive the plurality of their primary care services from a primary care physician in the ACO. But beneficiaries are still free to seek care from physicians outside the ACO. Physicians and beneficiaries will be notified of alignment prospectively, but calculation of shared savings will be done retrospectively.

The proposed rule also requires ACOs to notify beneficiaries of alignment at the time services are delivered and post signs in facilities of participating providers/suppliers indicating participation in the Shared Savings Program. ACOs are also required to make standardized written information available to aligned Medicare beneficiaries who will receive services from that ACO.

No Lock-In

We strongly support CMS's decision to allow beneficiaries to seek care outside of the ACO if they desire. This provision provides important reassurance to Medicare beneficiaries who can be wary of change. Negative experiences with early Medicare+Choice plans are still fresh in the minds of many, and if beneficiaries believe they are being "locked in" to a new system without their consent they are likely to reject it out of hand – jeopardizing the potential advantages that ACOs may bring to patients and the health care system. We do not want to repeat the now infamous backlash against past models of "managed care." Patients want their providers to be "gateways", not roadblocks, to high quality care. If ACOs are doing a good job of providing patient-centered care that is comprehensive, high quality, and well-coordinated, and they are creating regular opportunities for patient and caregiver feedback on their experience and outcomes of care, then ACOs are likely to provide desirable care that patients and families embrace. As patients experience better and more affordable care, trust levels will increase and "lock-in" will not be necessary.

Non-Interruption of Care

CMS should ensure that beneficiary alignment with an ACO does not create interruptions in ongoing care that cause significant hardships for beneficiaries or result in a reduction of needed services.

Full Transparency and Notification

We believe that there must be full transparency of beneficiary alignment with an ACO. Beneficiaries have a right to know about any new financial incentives that may influence provider behavior and the care that is delivered. Beneficiaries also need to fully understand what they can expect from the ACO including attributes that differentiate it from the current fee for service model like improved care coordination.

ACOs, in conjunction with doctors, should provide patients with written descriptions of the shared savings arrangement as soon after alignment as possible. The information should be written in a way that patients can understand, and it should also clearly communicate what patients can and should expect from the ACO and its providers. It should also provide beneficiaries with information on who to contact when their expectations are not met.

CMS should develop model language that describes, in accessible language, the benefits, beneficiary rights, and beneficiary and provider responsibilities in an ACO. This language should be used in all ACO beneficiary notices, and it should be included in the Medicare handbook and on the Medicare.gov website. Model language should be developed in consultation and with input from consumer groups, beneficiaries, and family caregivers.

Model notice language should be translated into those languages – other than English – spoken by at least 5 percent of the ACO members. For ACO members who speak languages for which materials are not translated, the ACO should provide oral communication of this information utilizing either competent bilingual staff or interpreters. These notices and other important information should be crafted in a culturally and linguistically appropriate manner and at a literacy level no higher than 5th grade.

An ACO's website should also include information for members who speak languages other than English. The website should include translated information or taglines that give a limited English proficient individual a telephone number to call to access information in non-English languages either through the use of competent bilingual staff or interpreters.

The ideal way for patients to learn about ACOs is through conversation with their physicians or trusted care team members. When notifying beneficiaries, ACOs should be encouraged to coordinate with beneficiaries' aligned primary care physicians to the extent possible – e.g. naming the physicians and encouraging beneficiaries to talk with their physicians. CMS should also consider creating tools to aid physicians and other care team members in talking to patients about their ACO.

We also recommend that the ACO notify beneficiaries as soon as the alignment is made and not wait until a beneficiary receives services. This will help ensure that beneficiaries have ample opportunities to prepare questions for their physicians and reduce the likelihood that beneficiaries will receive information through hearsay. It also would enable CMS to more promptly share beneficiary data with aligned physicians.

Patient-Centered Care - §425.5(d)(15)(ii)(A)

One of the most important provisions of the proposed rule is the requirement that ACOs meet eight specific criteria in order to be considered patient-centered. We strongly support this requirement and urge CMS to maintain it in the final rule.

Critical Elements

A truly patient-centered health care system must be designed to incorporate features that matter to patients—including **whole person care** across the continuum of providers, settings, and patients' evolving health care needs; **coordination and communication**; **patient support and empowerment**; and **ready access** that ensures all patients get the right care, at the right time, in the right setting. These features are essential for ensuring that patients achieve better outcomes and higher levels of engagement. They are also essential to reducing costs due to things like preventable hospitalizations, medication errors, and duplicative tests or procedures.

The Campaign for Better Care (CBC) – with considerable input from the consumer community – developed a set of patient-centered elements that we believe is integral for an ACO to be patient-centered. These elements build on the earlier patient-centered principles developed by the National Partnership for Women & Families that are cited in the proposed rule. These patient-centered elements are the "yardstick" consumers will use to measure how effectively an ACO meets the needs of patients. A copy of the complete CBC "Yardstick for Better Care" is included in the addendum.

The proposed rule incorporates many of the elements the CBC has identified as being critical:

- care that is comprehensive and coordinated;
- > patient's experience of care routinely assessed and improved;
- a process for evaluating the health care needs of ACO patients and developing appropriate care plans;
- > systems to identify high risk individuals;
- > processes to ensure care coordination across providers and settings;
- > mechanisms for allowing beneficiary engagement and shared decision making;
- standards for beneficiary access and communication; and
- > internal processes for measuring clinical performance.

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 strongly urge CMS to further 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.

Care Coordination - §425.5(d)(15)(i)(D)

The proposed rule requires ACOs – as part of the application process – to have a mechanism in place for the coordination of patient care. We strongly support this requirement. Good care coordination is particularly important for high risk, high cost populations such as older adults who suffer from multiple chronic conditions and cognitive impairments.

As the Medicare population grows – and the average age of beneficiaries rises – the number of people with multiple chronic conditions is increasing significantly, thereby making the need for effective coordination even more critical. Older adults with multiple (five or more) chronic health conditions make an average of 37 doctor visits, see 14 different doctors, and fill 50 separate prescriptions each year.¹

As the number of doctors and specialists involved in a patient's care increases, patients find it more difficult to coordinate their care.² As a result, large numbers of older adults with multiple chronic health conditions report duplicate tests and procedures, conflicting diagnoses, contradictory medical information, and adverse drug reactions. They are more likely to experience preventable hospitalizations and are more susceptible to errors when they are in the hospital, which then makes them more likely to experience permanent loss of functional status.³

Care Coordination Processes

We strongly recommend that CMS require ACOs to detail the kinds of processes they will use to coordinate the care of Medicare beneficiaries. In particular the ACO should indicate how it will conduct an initial assessment, develop a care plan, share it with other care team members (electronically when possible), and then periodically review and modify the care plan. It should also indicate the procedures it will put into place to effectively monitor and manage tests, referrals, and procedures. It should indicate the type of medication management program that will be available. And it should indicate how it will accommodate the needs of patients with physical or cognitive limitations, language or cultural differences. The ACO should be able to obtain additional funding to pay for language services or for patients whose needs may be higher due to physical, cognitive or cultural differences. We strongly urge that ACOs describe the methods they will use to provide the comprehensive coordination of services, including for example use of home-based primary care services, necessary to effectively manage

http://www.rwjf.org/files/research/50968chronic.care.chartbook.pdf

¹ Berenson, R. & Horvath, J. (2002). The Clinical Characteristics of Medicare Beneficiaries and Implications for Medicare Reform. Prepared for: The Center for Medicare Advocacy Conference on Medicare Coordinated Care, Washington, DC. Retrieved from: <u>www.partnershipforsolutions.org</u>

 ² National Academy of Social Insurance (2003). Medicare in the 21st Century: Building a Better Chronic Care System. Washington, DC. Retrieved from: <u>http://www.nasi.org/usr_doc/Chronic_Care_Report.pdf</u>
³ Anderson, G. (2010). Chronic Care: Making the Case for Ongoing Care. Johns Hopkins Bloomberg School of Public Health, Robert Wood Johnson Foundation. Retrieved from:

high risk populations. There are a number of effective models that ACOs can choose to connect with or incorporate, such as GRACE, Independence at Home, and PACE.

As noted in other sections of our comments CMS should also regularly monitor whether the processes outlined in the ACO's application are actually in place and over time assess achievement of care coordination goals. (Note: later in these comments we also call for effective care coordination measures).

Patient Engagement - §425.5(d)(15)(i)(B)

Success of an ACO will be dependent, in part, on the extent to which it engages patients and their families and makes them full partners in their care. Patients need and want to be partners with their clinicians.

Decision-making

Consumers value decision-making tools that they can use with their clinicians to make good decisions about their care. They want guidance from their doctors, but they also want complete, unbiased information that enables them to assess all of their treatment options; to discuss side effects, trade-offs, and costs; and to review the risks and benefits of various options, including alternative therapies. This desire reflects patients' awareness that one size doesn't necessarily fit all when it comes to health care. This is potentially good news for practitioners as they help patients navigate a medical world in which there is increasingly no right or wrong answers. It is also a potential platform for building patients' or consumers' understanding that because options and preferences vary, "more care" might not always be better.

Consumers also value services that help patients and caregivers better manage health conditions. Patients and caregivers want clinicians to work with them to develop and set health goals, and to support them in meeting those goals over time. They see this kind of self-management support as including linkages to culturally appropriate community-based services such as transportation, exercise programs, assistance with daily living activities, and condition-oriented support groups.

In our own research, having decision support tools and self-management services have been identified by patients as one of the three most important aspects of good care (along with communication and coordination).⁴

We strongly support patient engagement and urge CMS to strengthen this provision of the rule. CMS indicates it does not want to be too prescriptive in the application process. But we believe ACOs should be required to provide a meaningful description of the process and some of the tools it will use to foster patient engagement.

⁴Bechtel, C., and Ness, D.L. (2010). If You Build It, Will They Come? Designing Truly Patient-Centered Health Care. *Health Affairs 29*(5), 914-920

Further, CMS should regularly monitor whether the processes outlined in the ACO's application are actually in operation. Over time, the ACO and CMS should be able to assess achievement of patient engagement goals.

Self-Management Tools

ACOs should be encouraged to use evidence-based approaches when available to engage patients in their own care. One such approach is the Stanford Chronic Disease Self-Management Program (CDSMP) which is available across the United States. ACOs could, for example, tap into this nationwide infrastructure to increase health promotion and disease/disability prevention, and self-management support for people living with chronic conditions. CDSMP is a <u>low-cost</u>, <u>evidence-based</u> intervention that has been shown to improve self-management skills and health status, and reduce the need for more costly medical care.

Beneficiary Experience of Care - §425.5(d)(15)(ii)(B)(1)

The rule is proposing that ACOs implement a beneficiary experience of care survey and that an ACO's application describe how the ACO will use the survey results over time. Scoring on the patient experience survey would become part of the ACO's quality performance assessment.

Patient experience is an excellent indicator of how well care is being delivered and correlates with improved patient adherence, clinical outcomes, and clinician satisfaction. It is a priority for consumers because it is easily understandable to patients and it captures both care experience and care quality. It is especially important for patients who have multiple conditions and for whom condition-specific quality measures cannot provide an adequate picture of the total quality of care received. It is also an important mechanism for achieving more patient-centered care as it provides direct feedback from care recipients that providers can use to improve their care practices. Finally, the solicitation and use of patient-reported care experience is one more way to increase the likelihood that ACOs will be perceived by patients as meeting their needs.

Survey Tools

We support CMS' proposal to use the Clinician and Group CAHPS survey to capture patient experience. But we also recommend that CMS consider the need for additional development of the survey or other tools to assess experience of care across the continuum of ACO providers and settings.

Caregiver experience is also important to assess for those patients with cognitive impairments that prevent them from talking about their own experience. Caregiver experience can also provide insights into areas patients themselves may be reticent to discuss.

Translation and Literacy Levels

Regardless of the survey tool used it should be developed in a culturally and linguistically appropriate manner and at a literacy level no higher than 5th grade. The survey should be translated into the languages – other than English – spoken by at least 5 percent of the ACO members. For ACO members who speak languages for which materials are not translated, the ACO should provide oral communication of this information utilizing either competent bilingual staff or interpreters.

Further, we urge that ACOs be required to examine patient experience data by age race, ethnicity, gender, preferred language and disability status. This will enable targeted intervention for specific populations and will help ACOs reduce and eliminate health disparities.

Use of Real Time and Qualitative Data

Use of standardized patient experience surveys will be important for public reporting, comparative assessment and trend analysis, as well as feedback to providers and quality improvement. However, to truly achieve patient-centered care that leads to better patient outcomes, engagement, and patient-clinician relationships, real-time feedback from patients to providers is also essential. There are many approaches and tools already being used effectively to accomplish this, such as office-based questionnaires, patient/family advisory councils, informal focus groups, and tools like "How's Your Health." We strongly urge CMS to encourage providers to collect real-time patient and family feedback in all aspects of ACO care delivery, and to use that information for rapid quality improvement activities.

Individualized Care Plans/Integrating Community Resources - 425.5(d)(15)(ii)(B)(4)

Under the proposed rule ACOs will be required to have systems in place to identify high-risk individuals and processes to develop individualized care plans for targeted populations. We strongly support this provision and encourage you to think of it as a "shared care plan" which is jointly maintained and updated by patients and members of their care team.

Individual Care Plans

Individualized care plans are a core element of effective care coordination. They are a vital communication tool and enable a patient, the family, and the care team to work together to identify the patient's goals, needs and preferences, including goals of care, and to create a plan based on those factors. Care plans also gives patients a clear sense of what to expect, what to do next, what their options are, and how they can achieve the best outcomes.

We strongly support CMS's suggestion that care plans should also identify community resources. This is particularly important for patients with chronic conditions and their caregivers who are likely to need additional information and/or support. We suggest that, when possible, ACOs determine whether high-risk individuals are clustered in a particular geography/community and develop partnerships with local community organizations that can help the ACO better understand and serve the needs of that population.

Electronic Care Plans

Meaningful use 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 criterion will be demonstrated (e.g., will ACOs have to provide documentation of their systems and processes in their applications?). The final rule should 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. But ACOs need to move more quickly towards requiring the <u>electronic</u> exchange of summary and care plan records (which, we'd note, NCQA includes in its medical home standards). To accomplish this, we recommend that ACO participants be required to use ONC's Direct messaging capability, or something comparable. The Direct Project, funded and run by the HHS Office of the National Coordinator (ONC) has resulted in a set of standards, services and privacy and security policies that enable secure email between clinicians, and as such, 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 more.

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 percent of their patients accessing their health information online.

Treatment of Non-Elderly SSDI Beneficiaries

The proposed rule does not explicitly address the issue of Medicare beneficiaries eligible by virtue of Social Security disability, but how this category of beneficiary is treated by an ACO is important.

Medicare beneficiaries with disabilities are likely to face ongoing challenges if an ACO does not provide the services and supports they need to live as independently and productively as possible. Given high rates of health problems and relatively low incomes among Medicare's nonelderly disabled beneficiaries, the needs of this population require careful attention in the ACO model.

In their application to participate in the Medicare Shared Savings Program, ACOs must demonstrate their ability to coordinate care for individuals with disabilities. Significant coordination capabilities should include:

- Rehabilitation
- Long-term services and supports
- Services not required by Medicare beneficiaries over age 65 (e.g., maternity care, community resources)

We believe CMS should specifically identify beneficiaries with disabilities as a "high risk" population for which ACOs are required to develop individualized care plans and identify community supports (§425.5(d)(15)(ii)(B)(4)). Stratifying the reporting of quality measures according to disability status is a key way to ensure high-quality care for this population and we urge CMS to do so.

Given the unique needs of Medicare beneficiaries with disabilities, additional evaluation and oversight should be provided by CMS. The Medicare Beneficiary Ombudsman should pay particular attention to the experiences and outcomes of beneficiaries with disabilities within the Medicare Shared Savings Program. We also urge CMS to conduct an annual assessment of this population to determine the extent to which care is provided in an appropriate, culturally sensitive and competent manner by the ACO. To the extent a beneficiary in an ACO is receiving substandard or inappropriate care, both the beneficiary and the ACO should be notified immediately and a correction plan should be developed and implemented.

Health Needs of a Diverse Beneficiary Population - §425.15(d)(15)(ii)(B)(3)

The proposed rule requires that ACOs have a process for evaluating the health needs of its patient population and have in place a plan to address those needs.

We support this provision and believe that ACOs should, as part of this process, be directed to collect age, race, ethnicity, language, gender and disability data and use this data to identify and reduce disparities. We believe that CMS should also require ACOs to have:

- Systems in place to identify and update the languages spoken by limited English proficient individuals and processes to provide language services for these individuals at all points of contact with the ACO;
- Systems in place to identify patients from different backgrounds (including race, ethnicity, language, gender, disability and LGBT status) and provide culturally appropriate care and information to these individuals at all points of contact with the ACO; and
- A process in place (or clear path to develop such a process) to exchange language information when patients transition to another provider or setting of care, both within and outside the ACO.

Risk Adjustment - §425.7

Preventing Risk Selection

We appreciate the challenges CMS faces in developing an expenditure benchmark for ACOs. We are concerned that the approach outlined in the rule inadvertently gives ACOs an incentive to avoid high-cost or high-risk patients. We urge CMS to consider other approaches for establishing the expenditure benchmark.

We note that Option 2, as discussed in the preamble, provides greater protection for both beneficiaries and Medicare. Under Option 2, CMS would develop an expenditure benchmark based on beneficiaries who are actually attributed to the ACO in the first performance year – thus eliminating any incentive for the ACO to avoid high-cost beneficiaries in this year. The benchmark would then be updated in Year 2 and Year 3 to adjust for beneficiaries who are no longer attributed to the ACO (as well as for those who are newly attributed to the ACO). This update approach ties the benchmark to beneficiaries who are actually attributed to the ACO. It therefore reduces an ACO's incentive to avoid high-cost beneficiaries because the ACO would not be able to enjoy the "cushion" of their higher historical expenditures remaining within the expenditure benchmark.

We also believe that CMS should reconsider its decision to forgo updating the expenditure benchmark for changes in beneficiary characteristics during the performance period. This would be particularly important if CMS chose to calculate the expenditure benchmark under the Option 1 approach. By risk-adjusting the expenditure benchmark for the risk scores of attributed beneficiaries during the years of the ACO agreement, CMS could limit ACOs' incentives to avoid high-cost and high-risk beneficiaries. As proposed, the rule protects the Medicare program from any "up-coding" ACOs may do to inflate their expenditure benchmark, but leaves high-cost and high-risk beneficiaries without adequate protection against new incentives for ACOs to shed high-cost and high-risk beneficiaries, perhaps by "counseling out" or by ceasing to

offer services that are important to certain high-cost populations. CMS may also want to consider monitoring any potential for up-coding that might occur.

Testing Risk Adjustment Methods

We know that the methodologies for effective risk adjustment are evolving over time. Current prospective risk adjustment approaches explain approximately 15 to 28 percent of variation in health care spending across individuals.⁵ We believe that more accurate risk adjustment methodologies will ultimately benefit consumers because they will enable providers to be fairly compensated for caring for high-cost and high-risk individuals.

We therefore urge CMS to continue studying risk adjustment methods and to update the use of risk adjustment in the Shared Savings Programs as better methodologies are developed.

Monitoring ACO Avoidance of At-Risk Beneficiaries - §425.12(b)

The potential for shared savings can create an incentive for ACOs to avoid sicker and costlier patients. Ironically – these are the very patients who have the most to gain from an integrated system that provides comprehensive coordinated care.

We support the rule's proposal to monitor ACOs to identify any entity avoiding at risk beneficiaries, impose a corrective action plan on any ACO found to be avoiding beneficiaries and, if necessary, terminate the ACO.

CMS is soliciting comments on whether lesser sanctions may be appropriate. We believe that a corrective action plan, followed by termination if behavior has not changed, is the only remedy that should be included in the regulation. The addition of lesser sanctions – such as a reduction in the alignment of new enrollees – may not be enough to prevent an ACO from seeking only the healthiest and least costly patients. The combination of corrective action plan and termination is the compliance standard used throughout the regulation and there is no reason to diverge from it here.

Access to Providers - §425.5(d)(13)

Under the rule an ACO will be considered to have a sufficient number of primary care physicians if the number of beneficiaries historically assigned to the ACO over the threeyear benchmark period exceeds a 5,000 beneficiary threshold. The rule proposes that if an ACO falls below the 5,000 beneficiary threshold during the course of the agreement period CMS would issue a warning and place the ACO on a corrective action plan. We

⁵ American Academy of Actuaries. (May 2010). Issue Brief: Risk Assessment and Risk Adjustment," Retrieved from: <u>http://www.actuary.org/pdf/health/Risk Adjustment Issue Brief Final 5-26-10.pdf</u>

urge CMS to have an evaluation plan in place for examining the reasons for the change and the impact on those beneficiaries still aligned with the ACO.

We strongly support the premise that ACOs be built on a strong foundation of primary care. Primary care is "rooted in the long tradition of general healers. These healers base their technical approaches on ongoing relationships and local knowledge of individuals, families and communities."⁶ ACOs simply cannot deliver patient-centered care without these attributes. Further, as noted in the proposed rule, primary care physicians may have the best opportunity to reduce unnecessary costs – by providing good preventive care, care coordination and chronic care management, thereby reducing duplicative or unnecessary tests and procedures, medication errors, avoidable hospital admissions or readmissions, and emergency room use.

Non-Physician Primary Care Practitioners

We are concerned that the proposed rule excludes patients being assigned to nonphysician primary care providers, such as physician assistants and nurse practitioners. We believe this is inconsistent with the intent 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. The impact of this provision could be to exclude communities that lack primary care physicians, and yet those communities could have a high proportion of patients who would particularly benefit from the improved coordination of care offered by an ACO. We therefore recommend that CMS expand its definition upon which assignment is based to include other providers of primary care services.

Full Care Continuum

It is also important that ACO providers are capable of delivering the full continuum of primary care services to meet the needs of the high risk and vulnerable populations they serve, including those that may need intensive care management and home-based primary care services linked with appropriate community-based supports and services. CMS should therefore ensure that ACOs have this capacity, and monitor whether high-risk populations are receiving the services that most effectively meet their needs.

Encouraging Providers Who Serve Dually Eligible Beneficiaries - §425.7

CMS has requested comments on strategies to provide preference to ACOs that serve a large dual eligible population. Dually eligible beneficiaries – individuals who hold health coverage through both Medicare and Medicaid – represent many of the individuals who most need the high-quality, well-coordinated care that may be furnished through an integrated system.

⁶ Stange, K.C., Miller, W.L., Nutting, P.A. Crabtree, B.F., Stewart, E.E. and Carlos, J.R. (2010). Context for Understanding the National Demonstration Project and the Patient-Centered Medical Home. *Annals of Family Medicine 8*(Suppl), s2-s8.

Dual enrollees are over 1.5 times more likely to experience serious health limitations, more than twice as likely to experience fair to poor health, nearly 3 times as likely to experience fair to poor mental health, nearly twice as likely to experience diabetes, and over twice as likely to experience asthma. Thus, dual enrollees are significantly more likely to experience not only worse health, but also worse health arising from conditions whose outcomes can be significantly improved through ambulatory care.⁷ Beyond ambulatory care and Medicare-covered services, dual eligibles are also more likely to live in a nursing home or other institutional setting – an indication of their higher level of impairment.⁸

We believe that any strategy for providing preference or incentives to ACOs that serve a large number of dually-eligible individuals should go hand-in-hand with heightened expectations for the ACO's capacity to serve these individuals as well as actual performance, including on measures that are stratified by race, ethnicity, language, gender, and disability.

Treatment of Duals

All ACOs – whether or not they have a high proportion of dual eligibles – should be able to manage and coordinate the full spectrum of dual eligibles' needs, and include within their network providers with expertise in managing this population's unique needs. CMS should specifically identify dual eligibles as a "high risk" (functionally impaired) population for which ACOs are required to develop individualized care plans and identify community supports (§425.5(d)(15)(ii)(B)(4)). We also believe that CMS should identify performance measures and performance targets specific to dual eligibles—e.g. standards for hospital admission rates for nursing facility residents or other measures indicative of performance in the quality domains for this population. And CMS should also encourage ACOs to include home health agencies, assisted living, SNFs/NFs and other providers of long-term services and supports in their networks to maximize coordination of care for dual eligibles.

Qualifications for Financial Incentive

We applaud CMS's interest in providing preferences or incentives to ACOs that serve dual eligibles. We believe, however, that simply serving large numbers of duals is not sufficient activity alone to warrant an incentive payment. We believe that ACOs that serve large numbers of these patients could warrant an incentive payment if they also build the structure necessary to serve dual eligibles and their unique needs, taking extra steps to coordinate care and benefits for these individuals. We also believe that dually-

⁷ Rosenbaum, S., Shin, P. (2011) Medicare's Accountable Care Organization Regulations: How Will Medicare Beneficiaries who Reside in Medically Underserved Communities Fare? Policy Research Brief #23, Geiger Gibson/RCHN Community Heath Foundation Research Collaborative. Retrieved from: http://www.gwumc.edu/sphhs/departments/healthpolicy/dhp_publications/pub_uploads/dhpPublication <u>6EFAAA15-5056-9D20-3DBE579D20C06F05.pdf</u>

⁸ Coughlin, T., Waidmann, T. and O'Malley Watts, M. (2009). Where does the Burden Lie? Medicaid and Medicare Spending on Dual Eligibles. *Kaiser Commission on Medicaid and the Uninsured*. Retrieved from: <u>http://www.kff.org/medicaid/7895.cfm</u>

eligible individuals could benefit from the improved care that can result from these efforts. We therefore propose a two-part test for qualification for any financial incentives:

- 1. The ACO's population of attributed beneficiaries includes a high proportion of individuals who are dually-eligible for Medicare and Medicaid (to be defined by CMS); and
- The ACO has built a delivery system designed to meet the unique needs of dual eligibles, as demonstrated by including Medicaid-participating providers among the ACO participants and ensuring these ACOs provide care coordination specific to dual eligible needs, including:
 - Coordination between Medicaid and Medicare benefits (e.g., when the programs have different standards or requirements for the same benefit or service);
 - Coordination between Medicaid and Medicare coverage (e.g., ACOs should adhere to balance billing rules);
 - Coordination support for high frequency dual eligible health needs (e.g., coordination and support for dialysis treatment, adult day care visits, etc.).

ACOs that serve primarily high-cost or functionally impaired dual eligibles may be expected to take further steps, such as:

- Incorporating a Medicaid health home as well as an ACO, or making other arrangements with Medicaid designed to integrate the full range of services duals need through effective models that ACOs can choose to connect with or incorporate such as GRACE, Independence at Home, and PACE, necessary to effectively manage high risk populations.
- Including within the network of ACO participants specialists with expertise in conditions more commonly experienced by dual eligibles, including cardiovascular disease, renal disease, mental illness and dementia. Networks should also include high frequency dual eligible health providers such as rehabilitation centers, dialysis centers, etc.

Options for Financial Incentives

For ACOs who have a high proportion of dual-eligibles among their attributed beneficiaries and who have built an appropriate system for these beneficiaries, potential incentives could include:

- Initial investment funding to off-set the costs of building this infrastructure and care coordination systems (if not possible under the regulation, this option could might be considered for pilots initiated under the CMMI);
- Increasing the shared savings rate for these ACOs (similar to the increase in the shared savings rate for FQHC visits, at §425.7(c)(7)); or

Exempting these ACOs from the 2 percent net savings threshold for the onesided model.

These incentives could be tiered in parallel with delivery system requirements. For example, an ACO that serves a broad range of dual eligibles (and includes Medicaid providers in its network) may receive a smaller increase in its shared savings rate than an ACO that serves predominantly high-cost dual eligibles and establishes a Medicaid health home to intensively coordinate their care.

Access for Rural Beneficiaries - §425.5(b)

The rule proposes to allow Critical Access Hospitals the ability to form an ACO independently but prohibits Federally Qualified Health Centers and Rural Health Centers from becoming ACOs. The latter two entities would be allowed to join as ACO participants in an ACO offered by one of the four statutory groups eligible to form an ACO. CMS claims that FQHCs and RHCs currently lack the required data elements (like service codes) in their payment and claims systems that CMS requires to both assign beneficiaries and determine expenditures during the contract period.

We are concerned about the impact of this decision on beneficiaries who live in rural areas. Of the nearly 19 million medically underserved patients served by federally qualified health centers nearly 1.4 million are Medicare beneficiaries. This means that some of the poorest beneficiaries with the greatest health risks – will not have access to the kind of care coordination an ACO can provide.

We strongly urge CMS to 1) ensure that ACOs that include FQHCs and RHCs are available in rural areas; 2) facilitate outreach between the ACOs and FQHCs/RHCs; and 3) work with FQHCs and RHCs to develop the capacity to become ACOs. In the meantime CMS should also establish a system for monitoring rural beneficiary access to ACOs.

Quality Measurement - §425.9

The proposed rule requires ACOs to meet quality and continuous improvement goals on measures of better care for individuals, population health, and spending in order to be eligible for shared savings.

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

Performance measurement is essential to: driving improvements in care; evaluating the quality of care ACOs deliver; and providing information that is useful to consumers. We support the measurement domains that CMS has established, as well as the stated intent to give additional focus to measures of outcomes, functional status, and patient experience. However, we believe additional focus is also needed in the areas of care

coordination and efficiency. Furthermore, we believe CMS should be expansive in its consideration of patient-reported data, which in addition to experience of care, should encompass patient-reported functional status and patient engagement. Patient reported data should also include data reported by family caregivers whenever appropriate.

In assessing whether CMS has identified an appropriate set of measures, we believe the key question is not how many measures are in the set, but whether the measures will enable us to achieve the goals of care improvement, accountability, and meaningful information for consumers. It is also worth noting that more than a quarter of the measures in the proposed set can be collected from survey or claims data, 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. The dashboard takes important steps toward addressing two parts of the Triple Aim - improving care and improving health. It does not, however, provide enough focus on making care more affordable. While meeting a cost benchmark will provide some insight into whether providers are reducing costs it is also important to understand how the cost reductions are achieved and to incorporate measures that ensure we are using our health care resources efficiently—to achieve best quality at lowest cost. This would include, for example, measures of appropriateness and episodes of care.

We strongly recommend that CMS strive for a core set of high-value measures that evolves over time as better measures become available.

Standardized Patient/Caregiver Surveys

We strongly support the requirement that ACOs conduct surveys of patients about their experience of care with their physicians. This is critical to ensuring that ACOs deliver patient-centered care. 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 adherence, care coordination, patient and family engagement, and other aspects of care. Moreover, patient experience is linked to improved health outcomes. Below are some specific recommendations for implementation of Clinician/Group CAHPS and other standardized surveys.

- 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. We encourage the development and use of supplemental questions focused on care coordination, shared decision-making, prevention, and meaningful use of IT as such questions are developed and validated over time.
- Standardized surveys should enable comparison across entities, and results should be made available to ACOs, ACO participants, consumers, and other stakeholders. Surveys should be designed to produce reliable results at the

individual physician level and they should enable aggregation to the ACO level. ACOs and ACO providers should be required to demonstrate that they are using results for quality improvement.

- Reporting at the individual provider level should be a participation requirement for the Shared Savings program. Public reporting is essential to reinforce professional motivation for quality improvement and accountability, to guide patient choice among ACOs and among physicians within ACOs, and to give health plans and others information to guide contracting and benefit design.
- While an annual experience survey will be important for public reporting and quality improvement, ACOs should also solicit real-time feedback from patients. Thus, CMS should also require ACOs to 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, and other approaches.

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 the Health Outcomes Survey, which 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. Readmissionsmeasured 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 riskstandardized, 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.

Standardizing Quality Measurement and Reporting - §425.10

We support standardizing health care quality measurement and reporting so that specifications for a particular measure are uniform – the same numerator, denominator, and exclusions – which will help consumers compare performance across providers. We support using NQF-endorsed measures whenever possible to promote consistency.

We also encourage CMS to promote consistency in measurement use across programs where the purpose of selecting the measure is the same. A provider enrolled in both the Medicaid and CHIP programs should not be asked to report on ten measures for Medicaid and ten totally different measures for CHIP; there should, instead, be a common core set with flexibility to add more as appropriate for the particular program. In identifying that core set, it should also be our goal to prefer outcome measures over process ones.

Improving Electronic Health Records Technology - §425.11(b)(1)

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 therefore support having 50 percent of eligible primary care providers be meaningful users of HIT as a core requirement for becoming an ACO. At the same time, we also believe that specialists and hospitals are critical players in delivering coordinated, efficient and effective care and focusing only on primary care ambulatory providers would leave these other professionals out. As an alternative to this requirement, CMS could examine the quality measures ACOs will report, and publish a list of the top 5 specialties that most affect the high prevalence chronic conditions that are reflected in the quality measures which would include, but not be 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.

While we understand the challenges hospitals face in becoming meaningful users, we also know the central role they must play in reducing readmissions, ensuring smooth transitions, and coordinating with primary and specialty care to improve health outcomes. At a minimum, all hospitals 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 facilitate this we encourage CMS to require hospitals to use the Direct standards, services and policies created by ONC. Direct 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, having an EHR 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 one should be a meaningful user or be registered for the program.

Grievances/Complaints Process - § 425.12(a)

The proposed rule requires CMS to use a range of methods to monitor ACOs, including an analysis of beneficiary complaints (§ 425.12(a)). We strongly support CMS monitoring complaints lodged against ACOs, but we urge CMS to establish a more formal structure for patients to voice grievances.

We believe CMS should require ACOs to have in place a formal grievance procedure. At present, as a condition of participating in the Medicare program, CMS requires hospices, ambulatory surgical centers and hospitals to establish a procedure for patients to voice grievances regarding treatment or care. The regulatory language for both Medicare Part D and Medicare Advantage is even more prescriptive, setting up specific grievance procedures that these plans must provide to beneficiaries in order to participate in the Medicare program (including a procedure for expedited grievances). We believe that CMS should require similar grievance procedures for ACOs participating in the shared savings program.

CMS should require ACOs to give notice to patients of their rights to file a complaint under the grievance procedures. CMS regulations already require hospices, ambulatory surgical centers, Part D Plan Sponsors, Medicare Advantage Organizations to give such notice to patients, and we believe this is an important part of beneficiary notification that should be included in the regulations under §425.5(d)(5) and §425.6(c).

CMS should also require ACOs to establish a process to track and maintain records on all grievances received and the disposition of each grievance. ACOs should report this information to CMS on a regular basis, and CMS should monitor grievances under § 425.12(a). If the amount or type of grievances raises concerns that the ACO is not providing adequate treatment to patients, CMS should have a process in place to issue warnings, put an ACO on a corrective action plan, or terminate the ACO's participation in the shared savings program.

We view patient grievances as an important indicator of patient experience and therefore urge CMS to consider grievance rates as part of its efforts to monitor ACO quality performance (§425.12(c)).

Beneficiary Data Sharing - §425.19 (g)

We support the proposed requirement that the ACO must inform beneficiaries of its ability to request claims data and to provide beneficiaries with the chance to opt out of data sharing.

However, some improvements should be made to the beneficiary notification and optout process. Rather than simply providing a beneficiary with a form and information for whom to contact to opt-out, the beneficiary should be able to tell someone working for the ACO at the point of service that they wish to opt-out and that person (the provider or office/hospital staff) should be responsible for passing that information along to the ACO representative who will contact the CMS data contractor. The beneficiary should then receive some sort of confirmation notice from the data contractor that they have been opted-out (and should be told to expect a confirmation and who to contact if they do not receive the notice in a set period of time).

The information should be translated into any language other than English spoken by at least 5 percent of the ACO members. For ACO members who speak other languages, the ACO should provide oral communication of this information utilizing either competent bilingual staff or interpreters.

Marketing Materials - §425.5 (d)(4)

We support the provision of the proposed rule that requires CMS to review all ACO marketing materials. It is imperative that consumers receive clear and accurate information about ACOs.

The proposed rule does not specify any prohibitions on ACO marketing activities. Although beneficiaries are aligned with ACOs based on where they get the plurality of their primary care services we are concerned that the ACO could make claims – beyond the promise of better care coordination – in order to keep a beneficiary aligned with the ACO for the purpose of shared savings. Therefore, we believe CMS should specify the prohibited marketing activities. There is precedence in both the Medicare Part D program and in the standards for Medicare Advantage organization marketing.

Specifically, we urge CMS to prohibit:

Providing cash or other remuneration as an inducement for remaining aligned with the primary care physician in the ACO;

- Offering gifts to beneficiaries;
- Engaging in any discriminatory activity such as, for example, attempts to solicit Medicare beneficiaries from higher income areas without making comparable efforts to solicit Medicare beneficiaries from lower income areas;
- Engaging in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the ACO. The ACO should not claim that it is recommended or endorsed by CMS or Medicare or that CMS or Medicare recommends that the beneficiary align with the ACO; or
- Engaging in any other marketing activity prohibited by CMS in its marketing guidance.

At the same time we do want to ensure that patient education materials and activities (e.g., social support, new tools for self-care) are not considered marketing materials or prohibited.

Anti-Trust Agency Review - § 425.5(d)(2)

Rural Exception

The Antitrust Policy Statement includes a "rural exception," where an ACO may include as an ACO-participant one *physician* per specialty from each rural county on a nonexclusive basis. We recommend that the rural exception be changed to include one ACO *participant* per specialty. Defining the rural exception in terms of participant rather than physician would allow an ACO to contract with groups of specialty providers in rural areas where specialists are working collaboratively. Preventing the ACO from contracting with more than one physician per specialty would inhibit rural Medicare beneficiaries from having access to the collaborative knowledge and skill found in specialty group practices. We observe that the concerns around market concentration are less significant in areas with a relatively sparse infrastructure of medical professionals. We therefore think that expanding the rural exception to include one ACO *participant* per specialty will not adversely affect competition within a rural market.

Conclusion

We appreciate the opportunity to share consumer perspectives on the proposed rule. And we look forward to working with you to ensure that ACOs – and all new care models – are designed in a way that truly transforms the way care is delivered to all patients.

Sincerely,

Advocacy for Patients with Chronic Illness, Inc. AFL-CIO AFSCME Alzheimer's Association American Association on Health and Disability American Hospice Foundation Caring from a Distance Center for Medical Consumers Center for Medicare Advocacy Community Catalyst Consumer Coalition for Quality Health Care Consumer Health Coalition Consumers Advancing Patient Safety (CAPS) Consumers for Affordable Health Care Consumers' CHECKBOOK/Center for the Study of Services Easter Seals Family Caregiver Alliance Florida CHAIN (Community Health Action Information Network) Georgia Watch Health Care For All Health Law Advocates, Inc Healthwise Kentucky Equal Justice Center Legal Aid Society of Southwest Ohio Medicare Rights Center Michigan Legal Services Missouri Health Advocacy Alliance Mothers Against Medical Error National Alliance for Caregiving National Coalition for Cancer Survivorship National Council of Jewish Women National Council on Aging National Family Caregivers Association National Health Law Program National Partnership for Women & Families National Women's Health Network North Carolina Justice Center National Partnership for Women & Families **Ohio Alliance for Retired Americans** OWL-The Voice of Midlife and Older Women The Commonwealth Institute for Fiscal Analysis (Richmond, VA) The Leadership Conference on Civil and Human Rights The National Consumer Voice for Quality Long-Term Care Virginia Interfaith Center Volunteers of America We Are The Uninsured in Cleveland Well Spouse[™] Association

A "Yardstick" for Better Care

Elements of Patient-Centered Practice for Inclusion in New Models of Care

Understanding patients' and caregivers' needs and preferences

- ~ Individualized care plans that reflect the patient's personal goals are developed in collaboration with the patient and authorized caregiver;
- Where appropriate, comprehensive geriatric assessments, including use of risk assessment tools and the evaluation of physical, emotional, social and functional capacity, are conducted;
- ~ Where appropriate, assessments of caregivers' needs are conducted;
- Care team conducts ongoing clinical monitoring, patients and caregivers are contacted periodically, and beneficiary advance directives are kept up-to-date; and
- ~ Patient decision tools are used to guide "shared decision-making" by patients/caregivers and practitioners.

Care coordination and management

- ~ An interdisciplinary care team is established and meets regularly;
- Patient information and medical history are current and available to the care team and patient and family caregiver;
- ~ Processes are in place to effectively monitor and manage all tests, referrals, and procedures;
- ~ Medications are actively managed and reconciled to avoid adverse interactions;
- Patient care transitions are planned, managed, and tracked, using appropriate tools, such as transition checklists, medication reconciliation, and care plans;
- The needs of patients with physical or cognitive limitations, language or cultural differences, and other issues that could impede access to care are identified and accommodated;
- Care team connects the patient and caregiver with community-based support services, as needed;
- Care team is available by phone, email, or in-person during evenings and weekends, and in-office appointments are scheduled promptly; and
- Ongoing assessments of care coordination strategies are conducted and plans for improvement are implemented, as needed.

Clinical outcomes and continuous quality improvement

- Any new delivery system pilot program or payment model should include ongoing assessment of clinical quality, appropriate public reporting, and implementation of continuous quality improvement programs;
- Robust clinical performance measures should be used to evaluate care delivery across the care continuum, and such evaluation should move quickly from today's generation of measures to encompass patient-centered outcome and experience measures;
- Performance assessment should include: measures of clinical quality patient outcomes, care coordination, avoidable hospitalizations, readmissions and ER use, adverse drug interactions, and resource use;
- Any new delivery system pilot program or payment model that creates new provider financial incentives should calculate rewards by weighing both quality measures and cost-savings;
- Race, ethnicity, primary language and gender data are collected and used to identify and eliminate disparities.

Patient/caregiver engagement and experience of care

- Patient and caregiver experience is evaluated frequently through patient surveys and the results are used both to improve quality and to inform patients and caregivers;
- ~ Aid is provided to help and support patients and caregivers in managing their conditions;
- ~ Provider performance on patient and, where practicable, caregiver experience of care surveys is used in calculating any provider financial rewards under new pilot programs or payment models.

Accountability

- Patients are notified of providers' and facilities' participation in any delivery reform pilot program or new payment model, including disclosure of any provider or facility financial incentives or shared savings opportunities;
- Patients are clearly informed of the opportunity to opt-out of any pilot program or new payment model;
- An external appeals process is available to patients whose providers or care facilities are participating in a pilot program or new payment model that offers providers/facilities the opportunity to profit from the savings generated for the Medicare program;
- The methodology for determining provider/facility payment under any delivery reform pilot program or new payment model should include risk adjustment to reflect differences in health status among Medicare beneficiaries;
- Before any pilot program is expanded to a broader population, a comprehensive, independent evaluation of quality and cost outcomes should be conducted, and its design should include comparison groups with similar demographic make-up located in areas with similar Medicare spending growth rates; and
- Decisions about expanding pilot programs, and the evidence to support the decision, are transparent and there should be opportunity for public comment to inform this decision-making.