FamiliesUSA
The Voice for Health Care Consumers

June 2, 2011

Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: File Code CMS-1345-P

Submitted electronically to http://www.regulations.gov

To Whom It May Concern:

Families USA appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) *Proposed Rule: Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations*, *CMS-1345-P*, published in Federal Register, Vol. 76, No. 67, pages 19528 to 19654, on April 7, 2011.

Families USA is a national, nonprofit, nonpartisan organization for health care consumers. Our mission is to ensure that all Americans have access to high-quality, affordable health care. Families USA has an interest in the protection of Medicare beneficiaries and strongly supports efforts to improve the quality of care delivered to Medicare beneficiaries while lowering costs. We believe that new models of care delivery and payment, including Accountable Care Organizations (ACOs), have great potential to improve care coordination and lead to comprehensive, patient-centered care. However, above all else, we believe in the importance of ensuring that beneficiaries and their needs are the focus of the delivery and payment systems implemented. It is essential that new delivery systems, such as ACOs, are more than a new way to pay health care providers.

We are very pleased with the high bar that CMS set in the proposed rule and strongly urge CMS to maintain the robust quality improvement and consumer protections in the final rule. In order to ensure that ACOs achieve their potential, it is necessary that CMS set the bar high from the outset and assist providers in achieving the high standards rather than set the bar at the lowest common denominator. While some stakeholders are concerned about asking too much of ACOs and individual providers, we believe that they must be held to a standard that is high enough to ensure they deliver high-quality, patient-centered care.

1201 New York Avenue, NW, Suite 1100 □ Washington, DC 20005 □ 202-628-3030 □ Fax 202-347-2417
E-Mail: info@familiesusa.org □ Web site: www.familiesusa.org

We are pleased that CMS will align ACOs with the triple aim of better care, better health, and lower costs. We also endorse the goals that ACOs should strive to achieve as set out in the preamble on page 19533, including “an ACO will put the beneficiary and family at the center of all its activities,” “an ACO will ensure coordination of care for beneficiaries regardless of its time and place,” “an ACO will attend carefully to care transitions,” and “an ACO will be proactive in reaching out to patients.”

We thank you for the opportunity to submit our comments and recommendations. Please feel free to contact me if you have any questions at mgady@familiesusa.org or 202-638-3030 (if I am out of the office, you may also contact Kim Bailey at the same number). We look forward to working with CMS as the Medicare Shared Savings Program and ACO models develop.

Sincerely,

Michealle Gady
Health Policy Analyst

Subpart A--General Provisions

§425.4 Definitions.

Marketing Materials and Activities:

We recommend that CMS revise the definition of "*Marketing materials and activities*" to add "electronic communications, including emails," and to add "other social media" after web pages to ensure that other ways of marketing to beneficiaries, including Facebook and Twitter, are included in the definition. With these changes the definition would read as follows (as indicated in bold):

> Marketing materials and activities include, but are not limited to, general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, **electronic communications, including email,** web pages **and other social media**, data sharing opt-out letters, mailings, or other activities conducted by or on behalf of the ACO, or by ACO participants, or ACO providers/suppliers participating in the ACO, or by other individuals on behalf of the ACO or its participating providers and suppliers when used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the Shared Savings Program.

We strongly recommend that CMS revise the definition of "*Marketing materials and activities*" to delete "informational materials customized or limited to a subset of beneficiaries" from what is not considered marketing materials. It is unclear what this is intended to reach and is overly broad. Inclusion of this language creates a significant marketing loophole for ACOs. For example, an ACO could develop materials highlighting the cardiology care provided by the ACO and send it only to its cardiac patients. While these materials would be informational in nature and limited to a subset of beneficiaries, they are clearly marketing materials and as such should be subject to CMS review and approval. Additionally, the other listed exceptions (ex.: flu shot reminders and billing matters) are comprehensive enough to properly exclude materials that are not marketing in nature from the requirement of CMS review and approval. With this change the definition would read as follows (as indicated by the strikethrough):

> The following beneficiary communications are not marketing materials and activities: ~~Informational materials customized or limited to a subset of beneficiaries;~~ materials that do not include information about the ACO or providers in the ACO; materials that cover beneficiary-specific billing and claims issues or other specific health related issues; or educational information on specific medical conditions (for example, flu shot reminders), or referrals for Medicare covered items and services.

Subpart B--Shared Savings Program Requirements

§425.5 Eligibility and governance requirements.

§425.5(b) Eligible Providers and Suppliers:

We are pleased that the Secretary exercised her discretion to expand the list of eligible providers to include other types of Medicare-enrolled providers and suppliers beyond those listed in the statute. It is important that ACOs coordinate care along the full continuum of care. Much of the discussion on ACOs has focused on the role of physicians and hospitals and how these providers will work together to improve quality and lower cost. Little attention has been paid to the need to include other providers, including post-acute care providers and long-term services and supports providers in the ACO structure. An ideal framework of an ACO would include primary care providers, specialists, hospitals, post-acute care and long-term services and supports providers, and community-based resources, based on the needs of the patient population served by the ACO. Medicare spending for post-acute care continues to rise and Medicare beneficiaries living in long-term care settings have disproportionately high Medicare spending. Integration, coordination, and aligned incentives among acute care providers and post-acute care providers and long-term services and supports providers will help address this trend.

We encourage CMS to study ACO formation and determine what changes, if any, are necessary to promote formation by and inclusion of the full range of health care providers in order to meet the needs of the beneficiary population served by the ACO.

§425.5(d)(3) Agreement Requirements:

§425.5(d)(3)(v):

We support the requirement that ACOs establish partnerships with community stakeholders in order to advance the three part aim of better care, better health, and lower costs. We agree with CMS that integrating community resources is an important part of delivering patient-centered care. We ask that CMS provide more guidance on what it means to partner with these resources. For example, partnerships could include organizing joint community forums, formal partnerships for service referrals, or health education campaigns.

While we support inclusion of community organizations on the ACOs governing board, and would recommend that CMS include this as a requirement, we object to CMS' plan to deem ACOs as having met the requirement to partner with community stakeholders simply by including a community stakeholder on the governing board. ACOs will serve a diverse population with a range of needs, preferences, and values. It is unrealistic to expect that one representative will be able to speak for the entire community on all issues.

We are also concerned with the examples that CMS provides for community stakeholders in the preamble on page 19550: "employers, commercial health plans, local businesses, State/local government agencies, local quality improvement organizations or collaborative." We think this list of organizations is overly narrow. While these entities are community stakeholders, they are different from community-based organizations, which we think ACOs should also include, since they often are the organizations that provide the types of community resources necessary for care coordination. In addition to the stakeholders listed by CMS, community stakeholders should include organizations within the community that provide social services and supports, such as organizations that provide meals to people in their homes, transportation service providers, assistance with insurance appeals and other health care access advocacy, health promotion and disease self-management, and language services. We urge CMS to require that ACOs develop partnerships with

community-based organizations as defined here: A community-based organization means an organization that a) operates within a single local or regional community; b) is representative of a community or significant segments of a community; and c) provides health, educational, personal growth and improvement, social welfare, self-help for the disadvantaged, or related services to individuals in the community.

We also recommend that in addition to requiring that ACOs explain how it will include these organizations, that CMS also develop systems to monitor whether ACOs are truly engaging community stakeholders in a meaningful way. Requiring the ACO to explain how it will partner with these organizations in its application is not enough to ensure that ACOs develop and utilize these partnerships.

§425.5(d)(4) Marketing Materials:

We support the requirement that marketing materials and activities be reviewed and approved by CMS before they are used with the beneficiary population. While it is important that ACOs communicate and engage patients, they must do so in a way that is clear and easy to understand and that does not make inaccurate or inappropriate claims to beneficiaries. We have seen egregious marketing behavior by private Medicare plans that have resulted in significant problems for beneficiaries. We do not want to repeat these problems with ACOs.

We recommend that CMS not only include a requirement that ACOs receive CMS review and approval of marketing materials and activities, but also explain, in regulation, what marketing activities are prohibited. Where appropriate, CMS should apply the Medicare Advantage and Prescription Drug Plan marketing regulations and guidance. We recommend that CMS include the following prohibited activities in the regulation:

- Providing gifts, cash, or other remuneration as an inducement for joining or remaining aligned with an ACO or with a particular provider within an ACO, particularly if this would result in the beneficiary changing providers,

- Engage in discriminatory marketing, such as marketing only to healthy populations or to beneficiaries that reside only in wealthy areas,

- Engage in activities that could mislead or confuse beneficiaries or misrepresent the ACO, including with regard to availability of services and supports in languages other than English,

- Claim that the ACO is recommended or endorsed by Medicare, and

- Engage in any marketing activity prohibited by CMS in guidance.

CMS must monitor ACO marketing activities. ACOs that fail to receive CMS review and approval of marketing materials or that engage in prohibited marketing activities should be subject to sanctions as set out in §425.13 and §425.14.

§425.5(d)(5)(ii) Notice of ACO Participation:

The language in this subsection currently reads: “(ii) Except as specified in paragraph §412.1(a)(1) of this section, all beneficiary communications, any materials or activities used by ACO participants, or ACO providers/suppliers on behalf of the ACO to communicate

about the ACO in any manner to Medicare beneficiaries, must be approved by CMS before use." We believe the reference to §412.1(a)(1) is an error. We believe this was intended to reference the definition in §425.4 of non-marketing materials and activities.

§425.5(d)(6) Tracks During Agreement Periods:

We are concerned about Track one (one-sided model) as currently structured and recommend that CMS revise this model. CMS proposes that ACOs that enter Track one share in savings during performance years one and two and then automatically change to Track two (two-sided model) and share in savings and losses in performance year three. While we understand CMS' reasons for proposing this option, as explained on page 19618 of the preamble, we are concerned about the potential harm to beneficiaries that could result under this option.

CMS proposes that ACOs explain in their application how they will migrate to a two-sided model by the beginning of year three and have in place ways in which to repay any incurred losses. However, this does not guarantee that when the time comes the ACO will in fact be ready to assume risk. This could lead to undercapitalized at-risk ACOs, which would have significant ramifications for beneficiaries.

We recommend that CMS revise Track one to include an evaluation at the end of year two to determine if the ACO is ready to assume risk. If the evaluation shows that the ACO is ready to assume risk, the ACO should transition to the two-sided model. However, if the ACO is not ready to assume risk, it should be permitted to complete the contract period under the one-sided model. The ACO should be given the opportunity to renew its contract for a second three-year period under either Track one or Track two. If the ACO renews under Track one, an evaluation should be conducted at the end of year two. If the ACO is still not able to assume risk, the ACO should be permitted to complete its contract under the one-sided model or be terminated, at CMS' discretion, but should not be permitted to renew its contract.

While the two-sided model is more likely to induce ACOs to control spending and improve efficiencies, and thereby increase savings in the Medicare program, these benefits are outweighed by the potential harm that would result to beneficiaries whose providers go out of business because they tried to take on risk and failed. There are many providers that are currently in a position to take on risk. However, there are many who are not in a position to do so and will need more than two years to change their practice patterns and business model in order to be in a position to take on risk. These providers should be given a reasonable amount of time to make the necessary changes.

§425.5(d)(8) Shared Governance:

§425.5(d)(8)(ii)(B):

We thank CMS for its commitment to patient engagement as evidenced by the requirement that ACOs include at least one Medicare beneficiary on its governing body. However, we recommend that CMS strengthen this provision and require proportional representation of Medicare beneficiaries on the governing body and include beneficiaries who qualify because of age and because of disability. Specifically, we recommend that CMS require two Medicare beneficiary representatives for every 5,000 patients assigned to the ACO, but no less than 15 percent beneficiary representation. As CMS acknowledges in the preamble on page 19549, limited beneficiary representation could be ineffectual. This is more likely if

participation is limited to a single beneficiary.

While a beneficiary advisory panel or committee may have value, it is inadequate, on its own, in providing for appropriate patient participation in ACO governance. A beneficiary advisory panel could serve as a resource to help the governing board, in particular the beneficiaries on the board, identify beneficiary issues and develop solutions and recommendations. But, even if an ACO has a beneficiary advisory panel or committee, it is necessary to also have beneficiary representation on the governing body to ensure that the ACO is responsive to the needs of the beneficiary population.

We recommend a structure in which there is proportional Medicare beneficiary representation on the governing body and a beneficiary advisory panel or committee. However, at minimum, ACOs should be required to have proportional Medicare beneficiary representation on the governing body and include beneficiaries who qualify because of age and because of disability.

§425.5(d)(8)(iv):

We support the requirement that ACO participants have at least 75 percent control of the ACO's governing body. Providers that need to access capital to make investments in needed infrastructure and staffing should be able to do so. However, the influence that such investors could have over the ACO should be limited. We have seen that some providers in the nursing home industry have become reliant on private equity firms and, in some cases, have been more responsive to their shareholders than to the needs of their patients. The 75 percent requirement should help mitigate the influence of such investors.

§425.5(d)(9) Leadership and Management Structure:

We support the strong leadership and management requirements that CMS has proposed, including clinical management and oversight by a medical director, a quality assurance and process improvement committee that oversees an ongoing quality assurance and improvement program, and development and implementation of evidence-based guidelines and processes.

§425.5(d)(9)(i)

In addition to requiring ACOs to submit documentation that demonstrates how the ACO will meet the leadership and management structures as part of its application process, we also recommend that CMS monitor the ACOs compliance with these requirements. It is not enough to require the ACO to explain how it will meet the requirements. Given the importance of these requirements, CMS must also monitor the ACO for compliance and take action to remedy any problems. For example, through site visits, CMS can monitor whether the ACO has implemented evidence-based medical practice or clinical guidelines and that the providers within the ACO actively use these guidelines.

§425.5(d)(9)(ix)(E)

We recommend that in addition to providing evidence that ACO participants comprise at least 75 percent of the governing body, that the ACO also be required to provide evidence of beneficiary and community stakeholder participation on the governing body. While CMS does not specify in the regulation what evidence ACOs must submit to demonstrate that ACO participants make up at least 75 percent of the governing body, we recommend that

whatever evidence the ACO presents to meet this requirement, it be required to present the same form of evidence of beneficiary and community stakeholder participation. For example, if the ACO identifies its participating providers on the governing board by name, the ACO should be required to provide similar information for beneficiaries and community stakeholders. Merely stating that the governing body will include beneficiary and community stakeholder representatives is inadequate.

§425.5(d)(9)(ix)(F)(8)

ACOs should be required to provide, as part of the application, descriptions of the remedial processes that will apply if an ACO participant or an ACO provider/supplier fails to comply with internal procedures and performance standards. CMS should know how the ACO will ensure that its providers and suppliers are meeting the performance standards and, if not, how the ACO will address this problem. Given the high level of accountability that ACOs have to beneficiaries and the Medicare program, CMS should ensure that whatever process the ACO has in place is adequate to help underperformers meet the necessary performance requirements.

§425.5(d)(15) Required Processes and Patient-Centeredness Criteria

Delivery of truly patient-centered care is an important element to an ACO's success. ACOs must deliver care that is respectful of the patient's values and preferences and that meets their needs.

Some important elements of patient-centered care include:

1. Developing and using an individualized health care plan through a collaborative effort with the health care team, patient, and caregiver. The care plan should reflect the patient's preferences and values, including the patient's primary language.
2. Patients should be empowered to participate in and manage their health care. An ACO must have in place systems and supports, including information and education about health conditions and treatment options in language the patients understand, to make it possible for patients to manage their health care and make informed treatment decisions. The ACO should also have systems and supports in place to help caregivers in their role in helping the patient manage his or her care.
3. Patients must be able to get access to care when they need it during and outside of typical office hours. This includes being able to schedule same day appointments when necessary, schedule appointments for routine care in a timely manner, and get access to care after hours. Patients should also be able to communicate with their providers in a language that they clearly understand, in a way that is easiest for them, including by telephone or via email.
4. Patients should have access to a health care coordinator with whom they can communicate effectively, who will help them navigate the health care system, understand their rights and responsibilities, answer questions, and help them understand their health condition and treatment options. Such a person will play an important role not only in ensuring that the patient receives the care they need, but also in relieving fear and anxiety.
5. Care coordination is a key component of patient-centered care. Care coordination should include:
    a. Coordination among all the patient's health care providers;
    b. Coordination among care settings, particularly during transitions between settings;

c. Coordination among payers, including Medicare, Medicaid, Tricare, and other forms of coverage; and
d. Coordination of health and social services, including transportation.

6. ACOs should also evaluate the health care needs of their patients and ensure that the ACO providers and suppliers meet the needs of the patient population, including post-acute care and long-term services and supports providers and providers that accept both Medicare and Medicaid.

We support CMS' decision to require ACOs to meet all 8 of the patient-centered care criteria set out in the regulation, rather than limiting it to the two criteria set out in the statute. The use of patient and caregiver assessments or individualized care plans, on their own, is inadequate to provide truly patient-centered care. We oppose limiting or narrowing the list of required criteria.

§425.5(d)(15)(i):

We support the requirement that ACOs provide documentation as part of the application that demonstrates how it will promote evidence-based medicine, promote beneficiary engagement, internally report quality and cost metrics, and coordinate care. ACOs should be required to provide more than a description of how these processes will be carried out. The documentation should include a sufficient level of detail, including an explanation of the tools the ACO intends to use, so that CMS can evaluate the effectiveness of each plan. CMS should also monitor the ACO's compliance with these processes and have mechanisms in place to ensure that the ACO is implementing the plans effectively.

§425.5(d)(15)(ii)(B)(1):

The beneficiary and caregiver experience of care should be a core component of the performance measurement on which ACOs are evaluated. We support the requirement that ACOs have a process in place to use a beneficiary experience of care survey and that the ACO describe how it will use the results to improve care over time.

We support CMS' proposal that ACOs use the Clinician and Group CAHPS Survey. We support the use of a single, standardized survey tool across all ACOs to allow for ease of comparison and to ensure that ACOs use a survey tool with adequate and reliable measures. We recommend that CMS consider adding as a requirement the use of the Cultural Competence Item Set for the Clinician and Group CAHPS Survey that the Agency for Healthcare Research and Quality recently released.

We support the requirement that ACOs also use a functional status survey.

We also recommend that CMS move as quickly as possible to require ACOs to implement a caregiver experience of care survey as well. Caregivers often are responsible for coordinating the care of the patient and often provide care and support for the patient at home. As such, caregivers are in an ideal position to provide valuable insight into the care that the patient is receiving. This is especially true for patients with cognitive impairments.

Data from experience of care surveys should be collected and reported by race, ethnicity, primary language, disability status, gender, and health condition. Analyzing data by health condition may help identify promising practices and areas for improvement. ACOs should be required to track the impact of care on different populations including dually eligible beneficiaries.

Experience of care surveys should be made available to beneficiaries in their primary language. When this isn't possible, the ACO should provide oral translation using bilingual staff trained to interpret or actual interpreters.

§425.5(d)(15)(ii)(B)(2):

We support this provision. (See comment above §425.5(d)(8)(ii)(B).)

§425.5(d)(15)(ii)(B)(3)

We support the requirement that ACOs have a process in place for evaluating the health needs of its patient population, including consideration of diversity, and a plan to address the needs of the population. However, as currently written, this requirement appears to apply only to the ACOs assigned population, which the ACO will not know until year two of the performance period.

Evaluation of the patient population and development of a plan to address the needs of the population should be done in advance of the performance period. Such an evaluation will be integral to determining the ACO's individualized care plan process and integration of community resources. We recommend that CMS revise this subsection to clarify that the ACO should not wait until year two to conduct such an evaluation of the patient population. This may require the ACO to use aggregate data provided by CMS of the ACO's historical population and/or the ACO's own patient files. Whatever data source is used, the ACO should conduct this evaluation in advance of the performance period and then reevaluate its plan based on the assigned population beginning in year two and each subsequent year.

§425.5(d)(15)(ii)(B)(4)

Individualized care plans are an important element of care coordination. We strongly support the requirement that ACOs have systems in place to develop individualized care plans for targeted patient populations. We support the requirement that care plans be tailored to the beneficiary's health and psychosocial needs, account for beneficiary preferences and values, and integrate community resources to meet the patient's needs (see comment above regarding §425.5(d)(3)(v) and community stakeholders). We recommend that the care plan also account for the patient's primary language.
We strongly support the requirement that care plans be developed through a process of shared decision-making that fully engages the beneficiary and the beneficiary's family and/or caregiver.

We support the requirement that ACOs submit a description of its individualized care plan program, along with a sample care plan, and an explanation of how the program will be used to promote improved outcomes for its patient population. The ACO should identify which patient populations it will target and explain in detail how it will engage these patients in developing an individualized care plan. We recommend that CMS have in place a system to monitor the ACO to ensure that it is following the program and utilizing individualized care plans.

§425.5(d)(15)(ii)(B)(5):

A critical element of high-quality, high-value care is care coordination. We support the definition of care coordination provided by CMS in the preamble on page 19547. However,

we think it is important to make clear that while clinical coordination is a necessary and important element of care coordination, care coordination is broader than clinical coordination. "Care coordination addresses potential gaps in meeting patients' interrelated medical, social, developmental, behavioral, educational, informal support system, and financial needs in order to achieve optimal health, wellness, or end-of-life outcomes, according to patient preferences."[1]

We support the requirement that ACOs have processes in place to promote care coordination. We urge CMS when reviewing ACOs processes to evaluate them based on the broad definition provided above and not just on clinical coordination elements.

We also urge CMS to closely evaluate how the ACO and its providers will address transitions of care, not only between health care settings and providers, but also transitions over time, such as between episodes of care or as a beneficiary's health status changes.[2] Beneficiaries and their families often need the most assistance during transitions. As a result, this is the point in time when failures in care coordination become the most obvious and problematic. Therefore, it is important that ACOs have effective protocols in place to coordinate care during transitions.

We strongly support the requirement that ACOs not employ strategies that would impede the ability of a beneficiary to seek care from providers that do not participate in the ACO. Beneficiaries must maintain freedom of choice of providers. We support the requirement that ACOs have processes in place to share summary of care information with providers both within and outside of the ACO and that they not impose any restrictions that are not legally required in the exchange of medical records with providers who are not part of the ACO. Where possible, the exchange of this information should happen electronically, using health information technology (HIT). However, the ACO should also have a process in place to exchange such information even if the provider receiving the information does not use HIT or an electronic medical record system.

CMS should require ACOs to provide a detailed description of the processes that will be used to promote care coordination. As we have noted in other areas, we urge CMS to implement a process to monitor ACOs to ensure that the ACO is following the processes set out in its application and to take necessary action where needed to ensure that the ACO implements care coordination processes in a meaningful way.

§425.5(d)(15)(ii)(B)(6):

While the Medicare population generally wants to be active participants in their health care, health literacy among this population is lower than in the non-Medicare population.[3] In order to engage beneficiaries and make them active participants in their health care, it is vital that they have easy-to-understand, objective information about their health condition(s) and/or treatment options.

We support the requirement that ACOs have in place processes for communicating clinical knowledge and evidence-based medicine to beneficiaries in a way that is understandable to

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1 Agency for Healthcare Research and Quality, *Care Coordination Measures Atlas*, AHRQ Publication No. 11-0023-EF, (Rockville, MD, December 2010), pg. 5, available online at http://www.ahrq.gov/qual/careatlas/

2 *Id*. at page 6

3 Medicare Payment Advisory Committee Report to the Congress, *Aligning Incentives in Medicare*, Chapter 7: "Shared Decision Making and its Implications for Medicare" (Washington: MedPAC: June 2010), available online at http://www.medpac.gov/documents/Jun10_EntireReport.pdf.

them. We particularly support the requirement that the information be presented in a way that is understandable to the beneficiary.

ACOs should be required to provide a detailed explanation of how its providers will communicate clinical knowledge and evidence-based medicine to beneficiaries in a way that is understandable to them. For example, the ACO should explain how it will ensure information is conveyed at the appropriate literacy level and in the beneficiary's primary language. This can be done by providing examples of the materials that ACOs will use as part of its application.

CMS may also consider assisting ACOs in this process by providing best-practices in conveying evidence-based medicine and clinical knowledge in an understandable way to patients.

As we have noted in other areas, we urge CMS to implement a process to monitor ACOs, such as site visits or audits, to ensure that the ACO is following the processes set out in its application and to take necessary action where needed to ensure that the ACO communicates clinical knowledge and evidence-based medicine to beneficiaries in a way that is understandable to them.

§425.5(d)(15)(ii)(B)(7):

Shared decision-making is an important part of patient engagement and provider communication. Health care providers have clinical information that beneficiaries do not, but patients know their values and preferences. Shared decision-making allows the patient to convey his or her values and preferences based on the potential risks and benefits of a given screening or treatment. Shared decision-making gives the beneficiary the opportunity to actively participate in his or her care, which will lead to more realistic expectations of screenings and/or treatment outcomes.

We support the requirement that ACOs have a process in place for beneficiary engagement and shared decision-making that takes into account the beneficiaries' unique needs, preferences, values, and priorities. ACOs should be required to provide a detailed explanation of the process for shared decision-making. For example, will the ACO use decision aids? If so, will they use decision aids developed by outside entities like the Agency for Healthcare Research and Quality (AHRQ), or will the ACO develop its own decision aids? How will the ACO survey the beneficiary's values and preferences? Will the ACO implement shared decision-making in primary care and specialty care settings? Will the decision aids include information about coverage and beneficiary financial obligations?

As we have noted in other areas, we urge CMS to implement a process to monitor ACOs to ensure that the ACO is following the processes set out in its application and to take necessary action where needed to ensure that the ACO implements shared decision-making.

§425.5(d)(15)(ii)(B)(8):

We support the requirement that ACOs have processes in place that allow beneficiaries to access their medical records. We ask that CMS go further and require ACOs to have a process in place that will allow beneficiaries to make corrections to information contained within their medical records.

§425.5(d)(15)(ii)(B)(9):

We support the requirement that ACOs have processes in place for measuring clinical or service performance by physicians across the practice and use these results to improve care and service over time. Better care is a central tenant of ACOs. Providers will only be able to improve care if there is a continual feedback loop that informs them of how they are doing and how they can improve the care and service they are providing.

§425.6 Assignment of Medicare fee-for-service beneficiaries to ACOs.

§425.6(c) Beneficiary Information and Notification

Regardless of whether assignment of beneficiaries to ACOs for the purpose of determining savings or losses is prospective or retrospective, transparency is key to beneficiary buy-in and the success of patient-engagement. Medicare beneficiaries are often wary of change. If beneficiaries feel they have been placed into a system not of their choosing and without their permission, they may reject the new system outright.

We appreciate CMS' requirement that ACOs provide notice to beneficiaries and that ACOs post signs in provider offices letting patients know that the provider is part of an ACO. However, this requirement is not adequate and should be strengthened. We strongly recommend CMS revise the proposed regulation to require notice to beneficiaries before the point of service. We disagree with CMS' statement in the preamble on page 19568 that it is not possible to provide beneficiaries with notice prior to when they seek service from the provider or supplier. ACOs can provide such notice either by using the data that CMS will provide ACOs (as set out in §425.19), by using its own patient records, or a combination of both.

Any notice to beneficiaries must be made in writing prior to the beneficiary's first appointment with the ACO provider or supplier. And it should be made in the beneficiary's primary language. If it is not possible to provide notice in the beneficiary's primary language, the ACO should provide oral translation using bilingual staff trained to translate or interpreters. The notice must explain that the beneficiary's provider is a member of an ACO and should clearly explain what this means for the beneficiary. It should include an explanation of the beneficiary's rights and responsibilities (including the right to see providers outside of the ACO and where to file complaints or grievances), what changes they may expect, how they will benefit, the provider's responsibilities and financial incentives, and where they can call to ask questions and get more information. The notice should be made by the provider, using CMS approved language.

At the time that CMS assigns a beneficiary to an ACO, CMS should notify the beneficiary in writing of such assignment. The notice should explain what this means for the beneficiary, the beneficiary's rights and responsibilities (including the right to see providers outside of the ACO and where to file complaints or grievances), and where they can call with any questions.

Notice prior to the point of service will provide a meaningful first step in the process of patient engagement. Providing notice prior to the point of service will give the patient time to read it carefully and contact the provider with any questions they may have. A notice provided at the point of service will not allow the beneficiary adequate time to read and understand the notice, nor will he or she likely have the time to ask any questions. Advance notice can also provide the patient with information about how to prepare for his or her next

appoint, including preparing a list of all medications and health care providers.

§425.7 Payment and treatment of savings.

Encouraging Providers Who Serve Dually Eligible Beneficiaries

There are currently at least 9 million "dual eligibles"—people who are enrolled in both Medicare and Medicaid. They are often the sickest and most vulnerable patients in the health care system. Among dual eligibles, 66 percent have three or more chronic conditions, and 61 percent have a cognitive or mental impairment.4 More than half of dual eligibles have incomes that are below the federal poverty level ($10,890 for an individual or $14,710 for a couple in 2011). They are also some of the most costly patients to cover. Dual eligibles account for 25 percent of Medicare spending and almost half of Medicaid spending, despite making up less than a quarter of total enrollment in these programs.[5]

Since neither Medicare nor Medicaid is responsible for coordinating care and benefits, and because of conflicts between the two programs, this population is the least likely to have access to coordinated care. Instead, they find themselves in a highly fragmented system. As a result, dual eligible individuals sometimes encounter problems getting the care that they need in the most appropriate setting, and they often receive duplicative or unnecessary tests and treatments.

Dual eligible beneficiaries would benefit significantly from a coordinated care model, such as an Accountable Care Organization. However, given their vulnerable status, dually eligible beneficiaries may need additional protections and assistance, including, but not limited to:

- **Marketing protections:** The dual eligible Special Needs Plan experience has shown that there must be strong marketing protections in place to ensure that this vulnerable population is not taken advantage of.[6]
- **Cost-sharing protections:** Dual eligibles are often inappropriately charged cost-sharing by providers who do not know that they must bill Medicaid for payment of Medicare copayments and coinsurance. Providers also often balance bill dual eligible beneficiaries even though they are prohibited from doing so. Any ACO that serves dual eligibles should be required to demonstrate as part of its application that all of its providers have been properly educated about cost-sharing responsibilities and balance billing prohibitions for the dual eligible population and have in place processes to ensure that beneficiaries are not inappropriately billed.
- **Provider adequacy:** ACOs that serve a large portion of dual eligibles must ensure that its providers accept both Medicare and Medicaid and are able to bill under both programs. These ACOs should also have either as participating providers in the ACO or through some other means have formal relationships with long-term supports and services providers (SNFs, Assisted Living, Home Health, etc.) and transportation service providers. These providers play significant roles in the health care needs of the dual eligible population.

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4 Kaiser Family Foundation Program on Medicare Policy, *The Role of Medicare for the People Dually Eligible for Medicare and Medicaid* (Menlo Park, CA: Kaiser Family Foundation, January 2011), available online at http://www.kff.org/medicare/upload/8138.pdf.

5 Medicare Payment Advisory Committee, *Report to the Congress: Aligning Incentives in Medicare*, Chapter 5: "Coordinating the Care of Dual-Eligible Beneficiaries," (Washington: MedPAC: June 2010), available online at http://www.medpac.gov/documents/Jun10_EntireReport.pdf.

6 David Lipschutz, Paul Precht, and Bonnie Burns, *The Reluctant Regulator: Centers for Medicare and Medicaid Services' Response to Marketing Misconduct by Medicare Advantage Plans*, (California Health Advocates and Medicare Rights Center, July 2007), Available at http://www.medicarerights.org/pdf/Reluctant_Regulator.pdf

- **Care coordination:** Dual eligible beneficiaries will need assistance not only in coordinating their health care, but also in coordinating their benefits. ACOs that treat dual eligibles should have dedicated staff to assist beneficiaries in navigating their benefits, including assisting beneficiaries in filing appeals when coverage is denied by either Medicare or Medicaid.
- **Cultural Competence and Language Access:** Many dual eligible beneficiaries' primary language is something other than English.[7] ACOs that treat dual eligible beneficiaries should be required to demonstrate cultural competency (for example by using the Cultural Competence Item Set for the Clinician and Group CAHPS Survey) and demonstrate that it will meet the needs of its patient populations' language access needs.

In order to encourage providers who serve a large portion of dual eligible beneficiaries to participate in the Medicare Shared Savings Program, CMS will likely need to address administrative barriers and provide financial incentives.

The Medicare and Medicaid Coordination Office is working to align administrative requirements under Medicare and Medicaid and recently issued a Request for Information seeking input on how best to align the two programs in six areas. This is an extremely important initiative broadly, but in particular with respect to ACOs that serve dual eligibles. An area that CMS will need to address is the persistent difficulties with billing under Medicaid. For example, some providers who are not Medicaid providers who treat dual eligibles, whether full benefit dual eligibles or partial benefit dual eligibles, are unable to bill Medicaid or face significant hurdles. These problems often result in dual eligibles being inappropriately charged cost-sharing. This is particularly an issue for Qualified Medicare Beneficiaries. While it would be ideal for ACOs that serve a large portion of dual eligibles to include only providers that accept both Medicare and Medicaid, this isn't likely to happen in all cases. Therefore, CMS will need to work with state Medicaid programs to establish a means to allow these providers to bill Medicaid.

CMS will need to work with the state in order to share Medicaid data with the ACO. Just as ACOs need Medicare data, those that treat a large portion of dual eligibles will also need Medicaid data.

CMS will also need to engage states on not only administrative matters, such as billing, but also on reimbursement. In order to address Medicaid reimbursement issues, CMS could consider entering into a shared savings agreement with the state under which the state agrees to invest some of the shared savings in increased reimbursement rates for providers participating in ACOs or CMS could consider an increased FMAP to the state that would be used to increase reimbursement rates to providers.
In order to be most effective, ACOs that serve dual eligibles should also be accountable for Medicaid covered services. A few states, such as Connecticut and Colorado, under the Center for Medicare and Medicaid Innovation contract for dual eligible integration demonstrations, are currently investigating the best way to use the ACO model to integrate care and financing for dual eligible beneficiaries. CMS should monitor these states closely and develop best practices for how to engage the state in dual eligible ACOs.

CMS will also need to consider financial incentives to encourage providers who treat a large

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7 California Medicare Part D Language Access Coalition, *Please Hold: Medicare Plans Leave Limited English Proficient Beneficiaries Waiting for Access,* (California, December 2008), Available at http://www.nsclc.org/areas/medicare-part-d/area_folder.2010-05-17.5076574896/Reports-and-Studies/please-hold-medicare-plans-leave-limited-english-proficient-beneficiaries-waiting-for-access/at_download/attachment

portion of dual eligibles to participate in ACOs. We caution CMS to not simply provide financial bonuses without any accountability. Otherwise, we will likely just repeat the experience of the Medicare Advantage program in which private insurers were given significant overpayments, but have done little to integrate and coordinate care for beneficiaries. Financial incentives that CMS could consider include the recently announced Advanced Payment Initiative through the Center for Medicare and Medicaid Innovation to provide certain ACOs with access to their shared savings up front in order to make investments in infrastructure and personnel. CMS could also consider providing ACOs with increased shared savings rates similar to those proposed to encourage inclusion of federally qualified health centers (FQHCs) and rural health clinics (RHCs) and exempt ACOs that treat a large portion of dual eligibles from the 2 percent net savings threshold.

§425.7(c)(4)(iv) Net Savings Threshold and §425.7(c)(7) Additional Increase to Shared Savings Rate

We support CMS' decision to provide a financial incentive to ACOs to encourage inclusion of FQHCs and RHCs. However, it is unclear that these incentives will be adequate. As currently structured, the ACO will only receive the additional shared savings percentage if a certain amount of its ***assigned*** population has at least one encounter with a participating FQHC or RHC. However, it is unlikely that the ACO's assigned population would have an encounter with an FQHC or RHC.

Assigned patients will be determined based on which primary care physician provides a plurality of their primary care services. Assignment cannot be based on services received at a FQHC or RHC. If a patient has a primary care physician from whom they receive a plurality of their primary care services, it is unlikely that he or she would have a reason to receive care from an FQHC or RHC. Therefore, conditioning the financial incentive on the assigned population seeking care from the FQHC or RHC makes the incentive illusory.

We recommend that CMS revise the incentive in a way that inclusion of a FQHC or RHC is adequate to qualify an ACO for the financial incentive and does not include the requirement that the assigned patient population have at least one encounter with the participating FQHC or RHC.

§425.8 ACO quality and continuous improvement goals

Quality improvement must be the hallmark of ACOs. As discussed in the preamble, the intent of the Medicare Shared Savings Program is to promote accountability to Medicare beneficiaries. Quality and performance measurement are key elements of accountability. Without such measurement we cannot be sure of the quality of care that beneficiaries receive and whether that care improves over time.

We commend CMS for linking quality improvement to shared savings. ACOs are intended to lower health care costs and generate savings. But they should not do so at the expense of the quality of care provided to beneficiaries. Linking quality measurement to shared savings is one way to ensure that this does not happen. ACOs should also have incentive to focus not only on creating savings, but also on improving quality. The link between sharing in savings and quality improvement will provide this incentive.

We strongly urge CMS to maintain this requirement. Without this requirement, we have serious concerns about ACO providers limiting access to medically necessary care in order to generate savings.

§425.9 Measures to assess the quality of care furnished by an ACO

We commend CMS for proposing a robust set of quality and performance measures. We urge CMS to maintain the currently proposed list of measures. We also support CMS' intent to expand and revise the list of quality measures over time as more experience is gained with ACOs and quality and performance measurement and reporting. The quality improvement effort should be a continuous, evolving process.

While some stakeholders have expressed concern about the burden that the reporting requirements place on providers, we believe that the benefit and importance of quality improvement outweighs any potential burden on providers. Only with robust quality measurement and reporting will CMS and the public be able to evaluate how ACOs are performing. Additionally, only with quality and performance measurement will providers really know how they are doing and what steps they need to take to improve the care provided to their patients.

§425.10 Calculating the ACO quality performance score and determining shared savings eligibility.

We strongly support the five quality measure domains that CMS has proposed and urge CMS to maintain these domains and measurements in the final regulation. The domains recognize that care coordination, patient engagement, and patient experience of care are fundamental elements of ACOs.

We also support equal weighting of these domains because each domain is of equal importance.

We support CMS' intent to align quality measurement and reporting requirements across the many different programs under Medicare and Medicaid. This will not only provide consistency for comparison purposes but will also alleviate the burden of data collection and reporting on providers.

§425.12 Monitoring.

In the preamble on page 19624 CMS states: "we anticipate close examination of ACOs that incur large losses to the Medicare program." We urge CMS to also monitor ACOs with significant savings to ensure that these ACOs are generating savings through improved care and efficiencies and not through avoidance of at-risk patients or withholding or limiting medically necessary care. We also recommend that CMS monitor ACOs with dual eligible beneficiaries to ensure that providers do not inappropriately shift costs to Medicaid in an attempt to generate Medicare savings. Finally, we recommend that CMS provide notice to beneficiaries assigned to or likely to be assigned to an ACO when the ACO is found to have violated certain requirements, such as marketing requirements or avoiding at-risk patients.

§425.12(a)(2)(iii) Analysis of Beneficiary and Provider Complaints

In the proposed rule, CMS states that one of the methods it will use to monitor and assess the performance of ACOs is analysis of beneficiary and provider complaints. We support this proposal and recommend that CMS establish a formal grievance and complaint process for beneficiaries.

CMS should establish a system similar to the Complaint Tracking Module used for Medicare Advantage and Prescription Drug Plans through 1-800-Medicare that beneficiaries can access to file any complaints against ACOs or ACO providers.

CMS should require that ACOs have a grievance process in place that beneficiaries can use to file complaints or disputes regarding treatment or care. Other types of Medicare providers, including hospices and Medicare Advantage and Prescription Drug Plans, are required to have such processes in place. We believe ACOs should be subject to similar requirements.

We support the policies and procedures for a complaints process set out in the NCQA Accountable Care Organizations Draft 2011 Criteria: ACOs must have written policies and procedures in place to:

1. Receive and document complaints from patients,
2. Investigate relevant patient complaints,
3. For complaints that are not relevant, triage and refer them to the appropriate parties and to the payer, if applicable,
4. Respond to patient complaints,
5. Notify and update patients on the progress of the investigation,
6. Resolve patient complaints,
7. Meet timeliness standards for responding to and resolving patient complaints

Patients should be informed that they have access to an external appeals process through Medicare. In addition, all of the elements listed above should be done in a timely manner, and ACOs should specify their planned response timelines based on the processes they establish for receiving, documenting, and resolving complaints. ACOs should respond to complaints in less than 30 days or sooner if the circumstances warrant. A patient should always be notified in writing that an investigation was conducted, the findings of the investigation, and any action taken by the ACO to address the patient's complaint. The ACO can communicate this information to the patient by phone, but a phone call should not replace written notification. Additionally, if the ACO is unable, for legal reasons, to notify the patient of the specific action taken, the ACO must still advise the patient that action was taken to address their complaint.

The ACO should be required to maintain records of complaints received and actions taken to resolve the complaint and should report this information to CMS.

Because complaints and grievances are a good indicator of patient experience of care, CMS should monitor the complaints that are submitted directly through 1-800-Medicare and the complaints received by the ACO. CMS should have a process in place to issue a warning, require a corrective action plan, withhold or limit shared savings, cease assigning new patients, or terminate an ACO if the amount or types of grievances indicate that the ACO is not providing appropriate care to beneficiaries or meeting the goals of the Medicare Shared Savings Program of better health and better care.

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

We strongly support this provision. We recommend that in addition to reviewing claims data to monitor for trends and patterns suggestive of avoidance of at-risk beneficiaries, that CMS also monitor characteristics of the ACOs patient population to determine if it is reflective of the patient population within the ACOs geographic area. This may help provide insight into

where the ACO is drawing patients from, which may be an indication whether the ACO is using discriminatory marketing to attract low-risk beneficiaries.

We support the proposal that ACOs be required to submit a corrective action plan and that CMS withhold shared savings during the probation period. We also support the proposal that ACOs will not be eligible for shared savings for the performance period attributable to the time the ACO was under the corrective action plan. We recommend that CMS expand the available array of sanctions that can be imposed when an ACO is under a corrective action plan because of avoiding at-risk beneficiaries to include no assignment of new beneficiaries and no marketing.

§425.12(c) Monitoring ACO Compliance with Quality Performance Standards

Given the importance of the quality measurements and reporting, we strongly support this provision. It is vital that ACOs accurately report complete quality data. Failure to do so should result in meaningful consequences.

§425.12(e) Monitoring Beneficiary Notification

We support this provision and recommend that CMS monitor all notices to beneficiaries, not just the notice about sharing claims data and the beneficiary's right to opt-out.

§425.12(f) Monitoring ACO Marketing Materials and Activities

We support this provision and strongly urge CMS to carefully monitor ACO marketing materials and activities. We also recommend that CMS expand the array of sanctions to include withholding shared savings, designating the ACO as ineligible for shared savings while under a corrective action plan, not assigning new beneficiaries, and/or prohibiting marketing activity while under the corrective action plan.

§425.13 Actions prior to termination.

We support the actions that CMS proposes to take prior to termination of an ACO, but recommend that CMS specify that while under a corrective action plan, an ACO may also be subject to other sanctions, including withholding of shared savings, ineligibility for shared savings, no assignment of new beneficiaries, and/or marketing restrictions or prohibitions.

CMS should have the full array of intermediate sanctions available, similar to those imposed on Medicare Advantage and Prescription Drug Plans while under a corrective action plan.

§425.19 Data sharing with ACOs.

We support CMS' proposal to share data with ACOs, including aggregate and individual claims data. This information will be invaluable to ACOs when determining the needs of its patient population, developing individualized care plans, and coordinating care.

§425.19(g) Beneficiary Opportunity to Opt-Out of Claims Data Sharing

We support the requirement that beneficiaries be given the opportunity to opt-out of having their individually identifiable claims data shared with the ACO. However, we strongly recommend that CMS revise the proposed opt-out process to make it less burdensome on

beneficiaries.

Instead of providing beneficiaries with a form that provides information about whom to contact to opt-out, this form should be the mechanism to opt-out. The form should explain what information will be shared, who the information will be shared with, who it will not be shared with, and what the information will be used for. The form should explain clearly that the beneficiary has the right to opt-out of this data sharing by indicating his or her preference on the form (for example by checking a box), signing it, and returning it to his or her health care provider. The health care provider should then be responsible for advising the ACO and/or CMS that the beneficiary has opted out of having his or her claims data shared with the ACO. The ACO or CMS should then provide written confirmation to the beneficiary that he or she has opted out of the data sharing.

The ACO should make this form available in the beneficiary's primary language. If this is not possible, the ACO must provide either trained staff or an interpreter that can provide oral translation of the form. The ACO should also have a designated staff person available to answer any questions that beneficiaries have regarding the data sharing and/or the opt-out notice.

§425.23 Public reporting and transparency.

We strongly support this requirement and commend CMS for requiring such a high level of transparency. This high level of transparency will enable beneficiaries to make informed decisions about where they seek their care. It will also ensure that ACOs are truly held accountable to beneficiaries. And, importantly, it will encourage improvement as ACOs are able to compare themselves to other ACOs.

We support the list of publically reported information, particularly the shared savings and losses data and the quality performance scores. We support public reporting of this information in a standardized format that is easy to understand. A standardized format will allow beneficiaries to easily compare different ACOs in their area. We support posting of this information by the ACO and CMS. The information should, at a minimum, be posted on the ACOs website and on the CMS website.