701 Pennsylvania Ave. N.W., Suite 700
Washington, D.C. 20004-2694
(202) 737-5980 • (202) 478-5113 (fax)

info@carecontinuum.org

June 6, 2011

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

Re: CMS-1345-P

Dear Administrator Berwick:

On behalf of the Board of Directors of the Care Continuum Alliance, I offer the following comments for consideration in response to the Proposed Rule on the Medicare Shared Savings Program: Accountable Care Organizations, issued in the *Federal Register* April 7, 2011 (Proposed Rule).

The Care Continuum Alliance aligns all stakeholders along the care continuum toward improving the health of populations. Through advocacy, research and education, the Care Continuum Alliance advances population health management strategies to improve care quality and outcomes and reduce preventable costs for the well and for those with and at risk of chronic conditions—goals closely aligned with the Administration's Triple Aim. The Care Continuum Alliance represents more than 200 organizations and individuals, including physician groups, nurses, and other health care professionals; hospital systems; wellness and prevention providers; population health management organizations; pharmaceutical manufacturers; pharmacies and pharmacy benefit managers; HIT innovators; employers; researchers and academics.

The Care Continuum Alliance strongly supports the goals of the Patient Protection and Affordable Care Act ("The Affordable Care Act") to transform health care delivery to improve health, improve care and reduce health care costs. Affordable Care Act provisions crucial to achieving these goals focus on community-based care, prevention and wellness activities, physician-led care models and patient protections and decision support. Our members view new care delivery and payment models, such as those Affordable Care Act Sec. 3022 envisions, as crucial to achieving these goals.

Today, Care Continuum Alliance members participate in real-world examples of care teams led by physicians who diagnose illness and establish evidence-based treatment plans that align with patient-centered care needs and practices. Extended teams of allied health professionals use an array of health information technologies and tools to implement and support those plans. Care is delivered at an individual level, but assessed, stratified and measured at a population level in accordance with best practices and quality measures. Appropriate care can be delivered, based upon an individual's needs, in a variety of settings, including the physician office, allied health clinics or the individual's home, either in-person or remotely. Because the

Affordable Care Act strongly aligns with the Care Continuum Alliance's mission and vision, our members applauded the Act's recognition of varied care settings, delivery models and intervention modalities. Our members share the vision of community-based care to meet the needs of individuals and emphasize, for the first time, the importance of prevention and wellness.

Our members applaud the Centers for Medicare and Medicaid Service's (CMS) efforts to implement Sec. 3022 of the Affordable Care Act regarding shared savings models and Accountable Care Organizations (ACOs). We appreciate the coordination of effort and alignment of programmatic work across agencies and priorities. Finally, we recognize CMS' need to carry out this provision within the bounds of the statutory authority Sec. 3022 provides.

We recognize that Affordable Care Act implementation is ongoing and that HHS and CMS have yet to develop numerous provisions related to such alternative care settings and delivery models. However, we have significant concerns that the Proposed Rule is unworkable and cannot achieve the goals of the underlying statutory provision. Specifically, the requirements for financial integrity, size and gain sharing provide little, if any, realistic opportunity for participation by the vast majority of physicians and hospital systems in the United States, which jeopardizes the Affordable Care Act goals outlined above.

The May 17 announcement of the "pioneer" ACO pilot programs may address some of the concerns outlined herein. The Care Continuum Alliance continues to review the regulatory materials associated with those programs and intends to submit additional comments. We remain strongly concerned, however, that the Shared Savings program, as outlined in the Proposed Rule, will require significant adjustment to permit participation by even the largest and highest-performing physician groups and hospital systems.

Our specific comments on the Proposed Rule are as follows:

Sharing Beneficiary Identifiable Claims Data – Section II (C)(3-6)
CMS states in the NPRM that it has received feedback from the Physician Group Practice (PGP) Demonstration and through other channels that current year beneficiary claims data would produce "a more proactive approach to coordinated care." CMS also recognizes certain legal and practical limitations on its ability to share this data. CCA members are concerned that the approach CMS proposes does not represent the right balance between these tensions. CCA believes CMS' proposed data sharing scheme will present a significant obstacle to achieving the statute's quality improvement and cost savings goals. CMS proposes providing only aggregate data sets and individual beneficiary identification data for an "expected assigned population"; and limiting beneficiary identifiable claims data sets to those beneficiaries who received a service from "a primary care physician participating in the ACO during the performance year" and have not opted out of sharing their claims data with the ACO.

Providing only aggregate data on "expected assigned" ACO beneficiaries during the benchmark period will not provide sufficient data to enable the ACO to perform timely assessment and intervention. Well-designed population health improvement programs depend on comprehensive, historical and current claims (and other) data on the entire patient population to identify and capitalize on opportunities for intervention. CCA proposes that CMS provide ACOs with two years of historical individual claims data on all expected assigned members of the ACO population, rather than limiting historical information to only beneficiary identification and aggregated claims data.

Although we appreciate CMS' recognition that timely data is necessary to improve care, its proposal to limit monthly beneficiary identifiable claims data sharing only to those patients who have seen an ACO participating primary care physician during the performance year is problematic for several reasons. First, patient visits to primary care physicians will be scheduled throughout a year. Therefore, the ACO might not receive data on high-risk patients needing case management and other interventions until the end of the year, when the visit takes place. Likewise, if the visit is at the beginning of the year, claims data could become unavailable at the end of the performance year, pending a patient's next annual visit to his or her primary care provider. Also, recent claims data would be valuable to a primary care provider before a patient's visit to best develop a care plan. By creating a confusing system of obstacles to determine whether patient data should be available to the ACO, CMS will prevent the development of effective workflow to analyze that data.

Of great concern is language in the Proposed Rule to permit individual Medicare beneficiaries to opt-out of sharing their Medicare claims data with an ACO while remaining an ACO patient. Certainly, CCA has previously supported, and our members generally prefer, opt-out methodologies to opt-in methodologies to reduce administrative burden and reduce patient confusion. However, in this case, CCA believes that allowing beneficiaries to opt-out of sharing Medicare claims data with their ACO would produce uncertainty and gaps in patient data and would result in provider penalties for costs due to factors outside their control. The Proposed Rule clearly explains that the disclosure of beneficiary-specific claims information is permitted by the HIPAA Privacy Rule provisions governing disclosures for ''health care operations'' and that consent or prior notification of beneficiaries is not necessary. It is difficult to predict how many patients will opt-out of sharing their claims data. Therefore, this provision creates a significant risk factor for new ACOs and could undermine their ability to effectively execute population health management strategies.

Without complete claims data, health risk assessment and case management for new patients becomes more difficult and uncertain, as providers may need to rely solely on patient-volunteered information. When patients are unable or unwilling to communicate their medical history, effective patient engagement becomes nearly impossible. It is unreasonable to hold ACOs responsible for reducing costs and improving quality in a subset of patients for whom they have no claims data. Therefore, CCA believes that if CMS retains the opt-out provision for data sharing, it should either not count opt-out patients toward an ACO's eligibility for shared savings or require those patients to leave the ACO entirely by seeing another provider.

CCA believes that prospective patient assignment to ACOs would avoid many of these complications. ACOs must have data on a controlled, predefined set of beneficiaries in order to properly manage and coordinate care. At a minimum, CCA urges that monthly beneficiary identifiable claims data be shared with ACOs on all "expected assigned" beneficiaries throughout the year to enable the ACOs to proactively coordinate and manage the care of their entire potential ACO population.

Prospective vs. Retrospective Beneficiary Assignment to Calculate Eligibility for Shared Savings – Section II (D)(3)

The ACO model is based on giving provider groups incentives to use care coordination and population health management systems and strategies to improve quality and reduce costs. This model of care requires that provider groups have the ability to proactively target at-risk patients for engagement in population health interventions, such as disease and care management programs. A prerequisite for scalable and effective patient targeting is a deep understanding of the needs and profile of the entire patient population and each member in it.

This is only possible by applying data analytics across a defined patient population. CMS proposes retrospective patient assignment to ACOs to capture all patients who become eligible for the Shared Savings Program throughout a given year. The Proposed Rule further outlines a limited system for sharing claims data for an "expected assigned population." CCA understands the Sec. 3022 goal to redesign practices in a way that benefits all patients and not just those in the assigned population. However, as outlined below, we believe the risks of retrospective assignment far exceed the benefits. In addition, it has been our members' experience that improving the care management process for an established patient population results in improved care management for all patients. Therefore, CCA recommends prospective assignment of beneficiaries to an ACO at the beginning of each performance year, along with the provision of comprehensive historical and ongoing claims and demographic data on this assigned population.

CCA believes that achieving the goals of the Triple Aim through ACO practice models will require population health management strategies to identify at-risk patients for personalized interventions. Patient engagement is a crucial aspect of managing health in a way that leads to significant cost savings and quality improvements. The first step in this process requires a health risk assessment (HRA) for each ACO beneficiary based on the most complete information available, including individual claims data. It is not feasible for ACO providers to engage in time and resource-intensive population health management strategies for a retrospectively assigned population with incomplete claims data. Population health management requires constant patient engagement over time, and providers must know which patients to target to maximize resources and measure results.

CCA believes that having a defined set of patients, prospectively assigned to an ACO each year for the purposes of shared savings calculations, will better enable ACO professionals to manage their patient population. CMS estimates that 25 percent of patients change their primary care provider from year to year based on its analysis of the PGP population. There could be many reasons for this discontinuity of care, including the lack of a true "connection" to their provider practice. CCA believes this high rate of patient churn argues in favor of prospective assignment, rather than against it. In a prospective assignment model, ACOs will have the opportunity to reach out to the members of their assigned population and attempt to create the connection that is so important to care coordination. As CMS notes, there are well-established methodologies to retrospectively adjust for variations in patient populations that could confound accurate calculation of shared savings. Through prospective beneficiary assignment, ACOs could know that a core group of patients whom they have treated for a least a year would count towards their shared savings payments. This would allow ACOs to gather sufficient clinical, claims and patient-volunteered data to create a health risk assessment and to engage the patient and realize savings from health management and care coordination,

In addition to the problems with retrospective assignment mentioned above, CCA is concerned that the risk of being held accountable retroactively, without the data necessary to successfully coordinate and manage care, will inhibit highly qualified organizations from participating in the Shared Savings program.

Quality and Other Reporting Requirements – Section II (E)(2)

For more than a decade, CCA and its member organizations have developed and promoted measurement methodologies to create accountability for health and health care outcomes in organized systems of care. Therefore, CCA appreciates the need for measures that accurately indicate the quality of care furnished by fee-for-service Medicare providers. We concur with the four tenets outlined in the proposed rule that measures used for the Shared Savings Program

should: consist of a mix of process, outcome and experience measures; be aligned across Medicare and Medicaid public reporting and payment systems; minimize the burden of data collection on providers; and be nationally endorsed by a multi-stakeholder organization.

CCA supports CMS' ongoing work to develop, measure and report quality measures through programs such as the Hospital Inpatient Quality Reporting (IQR) program, Physician Quality Reporting System (PQRS), Hospital Compare and the Electronic Health Record (EHR) incentive program. We also believe that quality reporting should be conducted as efficiently as possible to ensure consistency and reduce administrative burden. Therefore, we thank CMS for linking ACO quality reporting to PQRS to reduce administrative burden and improve coordination across programs.

However, we are concerned that the nature and number of new quality reporting measures in the ACO rule will prove too burdensome for potential ACO participants. A provider's ability to understand and report on new measures accurately will take time, particularly with the institution of a new quality reporting tool, the Group Practice Reporting Option (GPRO) for ACOs. The addition of multiple new quality measures not previously required through other CMS programs and, in some cases, not approved by National Quality Forum (NQF) or other independent bodies will add significant difficulty to implementation. Experience with HEDIS and other measures proves that it takes several years to develop measures that are consistently reported and commonly understood across providers.

CCA recommends streamlining the reporting requirements by focusing them on a core set of measures, ideally the existing PQRS reporting requirements. CMS states in the Proposed Rule that the quality measures proposed will likely require refinement. Therefore, CMS could begin the program with a more manageable set of already established quality measures and incorporate additional requirements later, in stages. This would enable CMS and the ACOs to benefit from the lessons learned during the initial roll out, adjust to the new reporting system and adapt to workflow changes inherent in care coordination. At the very least, required novel measures should not count in determining eligibility for shared savings for their first two years. As a general philosophy, new, untested measures should not negatively impact an ACO participant's Shared Savings payments in the initial years.

Health Information Technology – Section II (E)(2)
An example of one overly burdensome quality reporting requirement is seen in requirements for meaningful use of health information technology (HIT). As such, CCA proposes eliminating measures pertaining to meaningful use of HIT for group practices in the Shared Savings program—at least for the first three years. HIT can be a useful tool to promote quality care. However, meaningful use itself is not a clinical measure. In keeping with the goals of the ACO program to improve health for individuals and populations, CMS should place greater emphasis on outcomes measures and should not prescribe specific processes for achieving care quality improvements.

Risk Adjustment – Section II (F)(4)
CCA appreciates and agrees on the need for accurate risk adjustment as part of the shared savings calculations. Further, CCA agrees with the intent to rely heavily on the CMS-HCC model for the ACO shared savings risk adjustment calculations. However, CCA believes it is critical for the CMS-HCC model to be improved before application to ACOs.

CCA and its member organizations have previously provided input to the Medicare Advantage program staff on this topic without response. The Medicare Payment Advisory Commission

(MedPAC) and recent independent research have offered substantial additional confirmation that the current CMS-HCC model substantially overestimates the cost of low-risk/healthy beneficiaries and underestimates the cost of high-risk/chronically ill beneficiaries, primarily because of the lack of coding persistence in fee-for-service[1,2]. Specifically, the model maintains a limited timeframe for risk adjustment calculation by purging all chronic illness identifiers every Dec. 31 rather than carrying these identifiers forward for at least a second year. It is likely this limited timeframe results in overspending on healthy populations, as well as the assignment of high-risk/chronically ill beneficiaries to less-than-appropriate predicted risk deciles. CCA believes the current HCC risk adjusters should be modified to include two or more years of chronic disease codes to allow for more accurate identification and stratification of individuals for risk purposes.

Large Investment and Withhold vs. Deferred and Capped Shared Savings
CCA believes the regulation is highly problematic in assigning expensive investments to the ACO beyond minimal ACO start-up costs (i.e., surety bonds, marketing and compliance department costs, health IT investments). The regulation then proposes to withhold 25 percent of the shared savings bonus payments because the ACO *might* perform worse and owe the government money at some point in the future. Further, the regulation proposes to defer the shared savings bonus a minimum of 18 months and cap the size of that shared savings bonus. CCA believes that these criteria amount to the government significantly increasing the potential liability of the ACO while restraining its upside. CCA recommends that CMS address the fundamental balance sheet problem created by these roles or risk substantial disincentive to many of the organizations that might be ideal ACO candidates. At a minimum, CCA recommends that CMS consider dropping the 25 percent withhold requirement and advancing ACO interim projected shared savings bonuses based upon best available data. The interim payments can be reconciled at the end of the year (as is done in Medicare Part D.)

Limited Appeal Rights
The regulation proposes to limit the ACO's right to appeal CMS decisions with respect to quality measures, beneficiary assignment, eligibility for savings and termination for low-quality measures. It is unclear why CMS should seek to limit appeal rights and CCA urges CMS to give ACOs appeal rights comparable to those of other key CMS business partners. At a minimum, CMS should offer a legal argument for why ACOs should not be entitled full legal protections if disputes arise in these aspects of the program.

Summary
The Care Continuum Alliance and its member organizations and individuals have spent more than a decade developing and promoting the strategies, tools and structures to create scalable, measureable and accessible models of population health improvement that support the Triple Aim of improved care, improved health and reduced cost trend. We have seen models of population health improvement successfully deployed in provider groups and health plans across the country and it is our mission to promote a proactive, patient-centric focus across the care continuum. This can only happen if and when the principles of population health

[1] Medicare Payment Advisory Commission. Report to the Congress: Medicare payment policy. Washington (DC), MedPAC. March 1998.

[2] Frogner BK, Anderson GF, Cohen RA, Abrams C. Incorporating new research into Medicare risk adjustment. Med Care. 2011 Mar;49(3):295-300.

management are incorporated to emphasize communication and team-based health care delivery.

CCA strongly supports the intent of the Affordable Care Act and the Shared Savings Program and we appreciate the opportunity to comment on the Proposed Rule. However, we are concerned that, in aggregate, the problems in the proposed structure and requirements in the Proposed Rule will prevent even the most sophisticated, integrated health systems from forming ACOs. We recommend that CMS thoroughly re-examine its proposal and solicit stakeholder assistance in a redesign of the program. CCA stands ready to assist CMS personnel with any questions they might have regarding the changes necessary to facilitate proper population health management.

We appreciate the opportunity to provide comment on the Medicare proposed Shared Savings Program: ACO Proposed Rule.

Sincerely,

Tracey Moorhead
President and CEO