June 6, 2011

Donald Berwick, M.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Berwick:

On behalf of the Board of Directors and members of HIMSS, we are pleased to submit written comments to the Department of Health and Human Services’ Centers for Medicare and Medicaid Services (CMS) regarding the Notice of Proposed Rulemaking (NPRM) published in the Federal Register on April 7, 2011, entitled, “Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations” [CMS-1345-P, April 7, 2011]. HIMSS appreciates the opportunity to leverage our members’ expertise in commenting on the Medicare Shared Savings Program NPRM.

As you know, HIMSS is a cause-based, not-for-profit organization exclusively focused on providing global leadership for the optimal use of information technology (IT) and management systems for the betterment of healthcare. Founded 50 years ago, HIMSS and its related organizations have offices in Chicago, Washington, DC, Brussels, Singapore, Leipzig, and other locations across the United States. HIMSS represents more than 37,000 individual members, of which two-thirds work in healthcare provider, governmental and not-for-profit organizations. HIMSS also includes over 500 corporate members and more than 125 not-for-profit organizations that share our mission of transforming healthcare through the effective use of information technology and management systems. HIMSS frames and leads healthcare practices and public policy through its content expertise, professional development, and research initiatives designed to promote information and management systems contributions to improving the quality, safety, access, and cost-effectiveness of patient care.

Given the subject matter expertise of our membership, HIMSS is focusing our response on the following five areas:

- Eligibility and Governance
- Establishing the 3-year agreement with the Secretary
- Assignment of Medicare Fee-For Service Beneficiaries
- Quality Reporting and Other Reporting Requirements
- Shared Savings Determination

II. B. Eligibility and Governance

2. LEGAL STRUCTURE AND GOVERNANCE
   a. LEGAL ENTITY

The NPRM solicits comments on the proposal to require the creation of a legal structure and seeks input on other suitable legal structure requirements that should be added, including whether a requirement to create a separate legal entity would create disincentives to forming an ACO. Observing that innovation
can be derived from various forms of governance and entities, HIMSS encourages flexibility in defining “who” may be an ACO.

In addition, HIMSS suggests that the government consider provider and facility concerns about data ownership and liability associated with establishing and managing ACOs. For example, clarifying the provider-patient relationship that is created by “looking at the data”, and how an “ownership interest” stake will need to be defined between all the participating members in the ACO.

To help address this issue, HIMSS suggests that legal implications, lessons learned, and practices that are developing in the Health Information Exchange (HIE) community may be helpful to CMS. HIEs have had to address provider concerns about reviewing health information of a person who is not his/her patient, as well as whether there is any liability or obligation to 'provide care' for that patient.

5. AGREEMENT REQUIREMENT

HIMSS concurs with the CMS proposal to require a three-year partnership agreement between CMS and the ACO.

In addition, although HIMSS understands the need to create a disincentive on early termination of the participation agreement, we are concerned that the proposed disincentive may actually be a deterrent to those considering forming an ACO under this program. Using data from the Government Accountability Office (GAO) on the estimated total ACO startup investment and first year operating expenses for the anticipated number of participating ACOs, first-year investment averages $1.8 million per startup. Moreover, a recent analysis by the American Hospital Association estimated $11.6 to $26.1 million per organization for investments required to implement and sustain the elements necessary for ACO success.

Given the potential for high initial costs, some of which would likely be for necessary health IT infrastructure and related resources, the proposal to retain the 25% shared savings hold-back if the ACO terminates its agreement with CMS prior to the completion of the three years may prove to be an untenable risk when deciding to make the high cost investments necessary to create an ACO under this program. HIMSS understands that a hold-back is an important and potentially necessary to encourage ACOs to complete the full agreement period. The challenge becomes finding the appropriate balance between creating a disincentive for early termination, and creating the unintended disincentive to initial participation. HIMSS suggests CMS may want to consider a more appropriate hold-back of 7.5% - 10%.

9. PROCESS TO PROMOTE EVIDENCE-BASED MEDICINE, PATIENT ENGAGEMENT, REPORTING, AND COORDINATION

The statutory language establishing the Medicare Shared Savings ACO program stipulates that there are a number of requirements that ACOs must satisfy in order to be eligible to participate in this program. Several of these standards address how patient care is provided by the ACO, with a focus on processes and methods to: (1) Promote higher quality of care; (2) better coordinate care; and (3) meet the needs and concerns of patients and their families, including effectively engaging patients and their families in medical decision-making. The law requires an ACO to “define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.”
HIMSS Response to “Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations”  
[CMS-1345-P, April 7, 2011] Notice of Proposed Rulemaking

HIMSS applauds the recognition of the important role of health IT in the use of evidence-based medicine and the potential to coordinate care. As noted in HIMSS Public Policy Principle 1.10, HIMSS calls for federal programs to incentivize and make available care coordination activities among healthcare providers that serve those patients whose care is the most costly, such as patients suffering from more than one chronic condition, are located in remote locations, receive care from multiple providers, or require long-term care services, and those residing in medically underserved and health professional shortage areas. Care coordination activities should utilize health IT, especially telehealth, to promote best practices and preventative care. As such, HIMSS supports the inclusion of these technologies in the coordination plans to be set forth by the ACOs.

HIMSS sees a strong potential for health IT to engage the patient in their own care. As described in the HIMSS Public Policy Principle 7.3, HIMSS supports the use of health IT, portable technology, and social media to facilitate appropriate and timely consumer awareness; to facilitate and aid decision-making regarding privacy; increase patient/provider communications; reduce medical errors; increase patient safety; manage advance directives; improve the transparency of price, cost and quality; foster trustworthiness among stakeholders; and, positively impact the health and quality of life for all individuals residing in the U.S.

HIMSS concurs with CMS’ desire to support and promote innovation through the marketplace in a non-prescriptive manner, including when and how to use HIT. ACOs, whether under this program or as they are being created in the private sector, could serve as a laboratory for innovation in areas such as evidence-based care, patient engagement, and care coordination. However, CMS does run a risk of not describing the program well enough, thus limiting an ACO’s access to full knowledge of best practices or the latest models or data that would support meeting these three areas. HIMSS suggests that it would be helpful for CMS to have an objective set of criteria and ongoing evaluations in the areas addressed in this section of the NPRM in order to ensure that ACOs are creating and then executing their plans appropriately. HIMSS is also cognizant that a variety of definitions exist for terms such as “patient engagement,” “patient-centeredness,” and “evidence-based medicine”. HIMSS suggests CMS provide a clear definition of these terms, as we believe it would be very useful to ACOs.

The NPRM addresses a mechanism to support patient connectivity (e.g. remote monitoring and telehealth), but is silent on the roles and responsibilities of stakeholders in coordinating care across care modalities. As a multi-stakeholder organization, HIMSS recognizes there is a role for others who have relevant skills and experiences in supporting coordination of care, such as health plans, to work together. HIMSS suggests that in creating guidance to ACOs, CMS should include guidance on potential coordinating partners.

Given the main programs in place that seek to transform healthcare delivery in the U.S., we strongly encourage the federal government to coordinate efforts within and across federal initiatives. The ACO criteria should map to and align with other federal initiatives, including the National Health Care Strategy and Plan, the Medicare and Medicaid EHRs Incentive Programs (Meaningful Use), and the forthcoming National Prevention Plan. In this way, coordinating across value-based incentive programs leverages existing efforts, efficiencies, and knowledgebase. HIMSS members believe this would help to maximize innovation and efficiencies for all activities.
10. PATIENT CENTEREDNESS CRITERIA
   c. EVALUATION OF POPULATION HEALTH NEEDS AND CONSIDERATION OF DIVERSITY

The HITECH Act directs the National Coordinator for Health Information Technology to “assess and publish the impact of health information technology in communities with health disparities and in areas with a high proportion of individuals who are uninsured, underinsured, and medically underserved (including urban and rural areas) and identify practices to increase the adoption of such technology by health care providers in such communities, and the use of health information technology to reduce and better manage chronic diseases.”

HIMSS applauds the efforts across all of the Department of Health and Human Services to consider diversity. This includes the Office of the National Coordinator of Health Information Technology, and this NPRM which requires ACOs to describe their process for evaluating the health needs of their Medicare population with an eye toward caring for a diverse population.

HIMSS knows that patients and the healthcare providers who care for these populations deserve comparable support for electronic health information technology unaffected by race, ethnicity, gender, geography or health financing. We continue to support the promotion of health information and management systems’ contributions to improving the quality, safety, access, and cost-effective care across all settings and for all patient populations, including those in culturally diverse or in underserved communities. Some examples of HIMSS and our members’ engagement toward these goals include the activities of the HIMSS Latino Initiative, the HIMSS Diversity Business Roundtable, and our HIMSS Public Policy Principle 8.1, supporting grants and other incentives to establish Health IT Action Zones. Such Zones must demonstrate effective practices for promoting the adoption of health IT by licensed clinicians who provide care to patients in vulnerable populations, as well as by providers who care for patients who are medically underserved, including in rural areas, and are impacted by health and/or digital disparities.

HIMSS is mindful that our membership and others in the healthcare community are keenly aware of the importance of accommodating access in the healthcare setting. We recognize that awareness on this issue must continue to expand to the health IT components of care delivery, particularly as we move to engage the patient as a healthcare consumer. Issues that will be important to address include patient health literacy, physical and mental capability, culturally sensitive care, and patient education between provider visits. One of the many benefits of health IT is that the cost of producing information in variable languages and in a culturally appropriate manner is less than in the current paper environment. This provides opportunities for variations of consistent messages through culturally-appropriate mechanisms. Mechanisms to access patient healthcare literacy need to be incorporated in the provider workflow.

As has been previously noted, HIMSS concurs that a non-prescriptive approach supports innovation; we suggest that it would be helpful for CMS to have an objective set of criteria in these areas. An objective set of criteria from CMS will ensure ACOs have knowledge of existing healthcare community innovations, thereby enabling ACOs to create and execute their plans effectively. As such, ideas, like producing information in an understandable and easily-accessible form in a culturally-specific manner at the patient’s level of healthcare literacy, should be considered in guidance from CMS.
b. CONFLICTS WITH PROGRAM REQUIREMENTS

The NPRM proposes that all contracts or arrangements between or among the ACO, its ACO participants and ACO providers/suppliers, and other entities furnishing services related to ACO activities must be in compliance with the obligations under the 3-year agreement, including document retention and access requirements. CMS also proposes other requirements around data generation, including quality data or other information or data relied upon by CMS in determining the ACO’s eligibility for, and the amount of, a shared savings payment or the amount owed by the ACO. IT infrastructure will be critical to meeting these data collection, retention, and reporting requirements.

HIMSS suggests that an alignment of CMS and ACO IT initiatives would also facilitate clinical documentation with coding, billing, and receipt of payment as a means to leverage efficiencies and reducing the demands on infrastructure and human resources.

C. Establishing the Three Year Agreement with the Secretary

1. OPTIONS FOR START DATE OF THE PERFORMANCE YEAR

The NPRM solicits comment on any alternatives to a January 1, 2012 start date that would allow the greatest number of qualified organizations to apply to participate in the first year of the program.

Given the complexity of the proposed rule, and the potential that the final rulemaking will not be published until close to the January 1 potential start date, HIMSS cautions that a January 1, 2012 start date may create undue burdens on organizations. We suggest a start date of July 1, 2012.

2. TIMING AND PROCESS FOR EVALUATING SHARED SAVINGS

The rulemaking notes that determination of an ACO’s eligibility to receive a payment for shared savings will be based upon an analysis of the claims submitted by providers and suppliers for services and supplies furnished to beneficiaries assigned to the ACO. CMS also recognizes that there are inherent lags between when a service is performed, when a claim is submitted for payment, and when payment is made (“claims run-out period”). The NPRM proposes using a 6-month claims run-out to calculate the benchmark and per capita expenditures for the performance year.

HIMSS is concerned that this would pose too great of a gap in time for an ACO to utilize payment to support necessary health IT investment. We recommend a 3-month claims run-out period. If CMS uses a six-month claim run out, we strongly urge CMS to expedite subsequent evaluation of ACO performance and notification and payment of shared savings (penalties). And, we urge CMS to consider a program for advance payment of anticipated shared savings, as has been proposed for comment recently by the Innovation Center.

6. Sharing Beneficiary-Identifiable Claims Data

HIMSS concurs with CMS’ statement that sharing beneficiary identifiable claims data with ACOs will assist them in improving care for individuals, improving care for individuals, improving health of their populations, and reducing the growth in expenditures for their assigned beneficiary populations. HIMSS supports CMS’ intention to make available individual claims data for assigned beneficiaries for health care operations purposes, namely quality improvement and reviewing the competence and qualifications...
of providers. In addition, given that claims data often is the only source of information about a patient across multiple providers, we encourage CMS to permit the use of claims data for purposes such as care management. Limiting it use would undercut the ability of an ACO to reduce unnecessary tests, engage patients in wellness and disease management programs and otherwise manage care. HIMSS believes HIPAA regulations provide sufficient guidance in the use and protection of patient data.

D. Assignment of Medicare Fee-For Service Beneficiaries

3. PROSPECTIVE VS. RETROSPECTIVE BENEFICIARY ASSIGNMENT TO CALCULATE ELIGIBILITY FOR SHARED SAVINGS

HIMSS members have expressed concern that the proposed retrospective beneficiary assignment will create a challenge because providers will not know which patients are assigned to them until after the care has been provided. HIMSS recommends taking a prospective beneficiary assignment approach. If this approach proves unworkable, HIMSS urges CMS to at least include the process used in the Pioneer ACO model.

Finally, HIMSS requests that CMS consider special provisions to address ACO management and responsibility for Medicare beneficiaries assigned to an ACO based on the plurality of their care, but yet may receive the majority of their care from outside the ACO structure. Such situations may exist because of extensive travel from a home location and/or involve a seasonal residence in other cities, states, or countries.

E. Quality Reporting and Other Reporting Requirements

2. PROPOSED MEASURES TO ASSESS THE QUALITY OF CARE FURNISHED BY AN ACO

HIMSS is a member of the National Quality Forum (NQF) and a partner of the National Priorities Partnership (NPP). HIMSS supports the NQF endorsement process and recognizes the Measurement Application Partnership (MAP) to align the measurement requirements across multiple CMS programs. Of the 65 proposed quality measures, we suggest that CMS reduce the number of required measures, and align those selected with other CMS pay-for-performance and pay-for-reporting programs.

3. REQUIREMENTS FOR QUALITY MEASURES DATA SUBMISSION BY ACOs

a. GENERAL

HIMSS concurs with CMS that multiple approaches are needed to capture quality measures data and other metrics that will be necessary to improve care delivery. We look forward to future rule-making offering greater real-time data capture and transmission.

b. Group Practice Reporting Option TOOL

HIMSS suggest that CMS work as early as possible with EHR vendors, DIRECT HISPs and HIEs to support efficient interfaces between EHRs, HIE, and the Group Practice Reporting Option (GPRO) tool. Additionally, the Quality Data Model developed by NQF should be supported to standardize data collection.

Given the fact that the GPRO tool has been in use for some time, HIMSS suggests that it is a data submission tool that should be evaluated for expansion beyond GPRO.
5. INCORPORATION OF OTHER REPORTING REQUIREMENTS RELATED TO THE
PHYSICIAN QUALITY REPORTING SYSTEM AND ELECTRONIC HEALTH RECORD
TECHNOLOGY

Because of the early state of the meaningful use program and because of adoption of Stage 1 is not known
yet, many HIMSS members have expressed concern that the threshold of 50% of participating providers
need to be Meaningful Users may be too high. Some providers may not choose to participate in
Meaningful Use or be eligible to participate in the Programs, but still may be able to demonstrate the
requirements of meaningful use.

For those not participating in the EHR Incentive Programs, this alignment should not be a rate-limiting
factor. The ACO Program should not serve as a means to increase rigor for other programs. Eligible
Professionals (EPs) should be allowed to submit to the Physician Quality Reporting System (PQRS)
without participating in ACOs.

We commend CMS for responding to market forces and innovatively providing new approaches such as
the Pioneer Model.

7. ALIGNING ACO QUALITY MEASURES WITH OTHER LAWS AND REGULATIONS

As stated in our response to Section II.E.2, harmonization of the quality measures across different quality
bodies should be a major priority, recognizing that alignment and harmonization do not mean
equivalence, especially given that some programs may require different kinds of measures than others.
There is undue burden placed on providers today reporting on same/similar quality measures, but required
in different formats or time sequencing.

F. Shared Savings Determination

7. TECHNICAL ADJUSTMENTS TO THE BENCHMARK IMPACT OF BONUS PAYMENTS
AND PENALTIES ON THE CALCULATION OF THE BENCHMARK AND ACTUAL
EXPENDITURES

The NPRM notes the various in-place Medicare bonus and penalty programs. The NPRM proposes that
such programs and associated incentive payments would (for hospitals but not for Meaningful Use EPs)
affect actual expenditures and the benchmark, and thus an ACO’s ability to realize savings. Consistent
with statutory authority, the NPRM proposes to exclude Medicare expenditures or savings for incentive
payments and penalties for value-based purchasing initiatives such as the PQRS, the e-Prescribing
program, and the EHR incentives for eligible professionals under the HITECH Act from the computations
of both benchmark and actual expenditures during the agreement period. Because the statute does not
explicitly grant authority to exclude other payments – such as EHR incentive payments to hospitals, the
Hospital Inpatient Value-Based Purchasing Program, and EHR incentive payments to critical access
hospitals (CAHs) – these and others would be counted in both the computation of actual expenditures and
benchmark expenditures for Part A and B costs.

HIMSS members believe that the same rationale given for excluding Meaningful Use EPs must also apply
to Meaningful Use Eligible Hospitals (EHs). HIMSS concurs with the belief expressed in the NPRM that
it is important to ensure that these various programs’ incentives are properly aligned so that their
interactions support rather than impede each of the programs’ goals. Although the statute does not
explicitly exclude these and other payments from the baseline calculation, it does not prohibit exclusion. As such, HIMSS recommends that CMS use its discretionary authority to apply the incentive payments to EHRs under the EHR Incentive Program, as well as other similar incentives payments not covered under the statutory authority, from both the computation of actual expenditures and benchmark expenditures for Part A and B costs.

We look forward to continuing the dialogue between our members and the Department to ensure the development of an interoperable healthcare system to support healthcare transformation in the U.S. If you have any questions, please contact Thomas M. Leary via email or at 703.562.8814.

Thank you,

H. Stephen Lieber, CAE
President/CEO
HIMSS