322 Canal Walk
Indianapolis, IN 46202-3268
(800) 257-4762
(317) 261-2060
Fax (317) 261-2076
www.ismanet.org

President
Brent Mohr, M.D.

President-Elect
Thomas Vidic, M.D.

Immediate Past President
Frederick Ridge, M.D.

Chair of the Board
Gordon Hughes, M.D.

Board of Trustees
Syed Ali, M.D.
James Koontz, M.D.
Agnes Bacala, M.D.
Thomas Barley, M.D.
Chandra Reddy, M.D.
James Lewis, M.D.
Richard Feldman, M.D.
Vicki Roe, M.D.
A. Michael Sadove, M.D.
Gordon Hughes, M.D.
Melany Rookstool, M.D.
Michael Keenan, M.D.
Shawn Swan, M.D.
Rhonda Sharp, M.D.
Kathleen Delnay, M.D.
Michael Sha, M.D.
(Young Physician Society)
Mary Baker, M.D.
(Resident and Fellow Society)
Paul Haste
(Medical Student Society)

Executive Vice President
James McIntire

SUBMITTED ELECTRONICALLY AT http://www.regulations.gov

June 6, 2011

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

Re: CMS-1345-P
Shared Savings Program: Accountable Care Organizations
Comments to Proposed Rule

The Indiana State Medical Association appreciates the opportunity to submit comments on the Shared Savings Program ("Program") Proposed Rule. Throughout the Proposed Rule, CMS states its desire to have health care providers participate in the Program. If it is truly the goal to transform how care is delivered, it should be in a way that encourages participation, not in a way that discourages it. It should incentivize people and not penalize them. Good care should be rewarded, but adding paperwork and administration merely creates more costs and puts it squarely on the backs of health care providers. CMS should be considering how to make health care cost effective. Adding complexity does not do that. Every rigid program layer further distances health care providers from the practice of medicine and patient care.

We are unable to estimate actual startup and maintenance costs for ACOs, but it is noteworthy that anecdotal reports from multiple large, sophisticated Indiana hospital systems is that their expenses in attempting to integrate their systems and implement, for instance, EHRs, have been astounding. For that reason, we doubt the reliability of the $1.8 million estimate, which alone is enough to discourage physician groups from creating ACOs.

Section II.A. Organization of the Proposed Rule
The definition of ACO stops short of providing an accurate description. The definition should also reflect that "ACOs will measure and report quality and maintain quality assurance and improvement processes."

Section II.B.1. Eligible Entities
The ACO's which include Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs) should not be given a higher percentage of any shared savings under the program. Most FQHCs and RHCs receive grants in addition to their increased fee-for-service reimbursement and most of them are nonprofits.

Section II.B.2.b. Governance
We reiterate our comments submitted on December 3, 2010. We believe it imperative that the governing board of each ACO consist of at least 50 percent of physicians who have their own practice and not physicians who are owned directly or indirectly by a hospital system. Although we recognize that the lack of participation by independent physicians could prevent this level of participation, we continue to support the idea that independent physicians have a significant and equitable role in ACO governance as they attempt to balance quality care and shared savings. This helps avoid conflicts of interest.

Section II.B.10. Patient Centeredness Criteria
Patient centered care as a criteria is commendable.

Section II.C.7. New Program Standards Established During 3-year Agreement Period
It is unfair to ask ACOs to commit to a three-year term to a burdensome program, take great steps to achieve it, and then reserve the right to change significant rules mid-stream.

At a minimum, ACOs need to know the terms and conditions of that commitment. Making them subject to future changes in, for instance, design, delivery and quality of care, and then shifting the burden to them to supplement their applications to address those changes, and then threatening them with sanctions for noncompliance is even more untenable.

Section II.D.5. Beneficiary Information and Notification
While we understand the goal of transparency with beneficiaries, you underestimate the confusion of this program. Patients will not understand this Program. It is well-known that patients ask for tests when they may not be needed, and that physicians sometimes allow them to satisfy the patients and reduce their liability. Now, patients may become skeptical (and unhappy) at the idea that their physician may be withholding care (e.g., tests) for self-gain. This will undermine the physician-patient relationship. (It could also unfairly influence quality scores in the patient/caregiver experience domain) And, because patients will not understand what or who an ACO is, they will distrust it and not want their information shared with the ACO and will opt-out of information sharing. This will hinder the ACO and its providers. Additionally, notifying beneficiaries that their provider is in an ACO at the time of service or that a provider is discontinuing participation in the Program will not necessarily mean that the provider is in the ACO to which the patient is assigned.

Therefore, this information will not have any value to the patient. What would have value is for the patients and providers to know at the time of service whether the patient is assigned to the ACO so the patient and the provider could truly work together to achieve better health for the patient in a cost-effective way. If patient notification is necessary, it should be provided by CMS, perhaps on EOBs.

Section II.E.2.a. Proposed Measures to Assess the Quality of Care Furnished by an ACO

ACOs should know all the criteria by which they will be measured for all three years at the beginning of their 3-year agreement.

Section II.E.2.c. Proposed Quality Measures for Use in Establishing Quality Performance Standards that ACOs Must Meet for Shared Savings

The 65 mandatory measures are too many. It should be less than 10 to give providers an opportunity to truly focus on reporting, measurement, and improvement in an administratively feasible manner. CMS should consider a two-prong approach to the quality performance standard. ACOs should be separately incentivized to accurately report all measures and also for their attainment level, with recognition for score improvement from past years, even if it does not meet CMS's minimum attainment level.

The largest area where this Program – and the health care system – misses the mark is patient accountability. There is none. However, this Program makes providers accountable for patient decisions. Providers cannot force patients to show up for appointments, participate in tests, control their diet, exercise, or properly take their medications. And yet all of these decisions are attributed to the provider. Although patient education is obviously important, it is not sufficient to alone contribute to significant behavioral changes or accomplishment of the Program's goals.

We will not discuss individually each of the 65 measures, although we do think that several deserve further consideration. We note that the inclusion of measure 24 Health Care Acquired Conditions is inconsistent with your statement that ACOs do not have to include hospitals. Measure 43 requires a dilated eye exam, but there are proven industry alternatives available to dilation (e.g., Optomap technology). Additionally, measure 28 mammography screening is inconsistent with the U.S. Preventive Services Task Force November 17, 2009 recommendation against routine screening until age 50. Although we disagree with their recommendation, the measures for this Program should be based on widely accepted and proven industry standards. We also think it is prudent to inquire whether vaccine supplies will be sufficient to meet demands so that providers are not unfairly penalized for industry shortages.

Section II.F.1. Shared Savings Determination
The investment and effort will not be worth the risk of participating in ACOs with shared losses. This is a significant concern for individual providers who could face liability for costs out of his or her control, including when patients go out of the ACO for care. It could also lead to the failure of independent physicians or small groups. One thing is certain: Entities participating in the Program will have more incentive to meet the goals of the Program than entities that do not. CMS should remove disincentives to participation. Create at least one track that does not include shared losses. This would help ensure that ACOs participate the full three years, since, as you note, "certain participating ACOs may choose to terminate their agreement early after the first 2 years" to avoid being subject to shared losses. This eliminates your suggested need for the 25% withhold and other payback assurances, which we also oppose.

It has also been noted that the Program does not reward providers who are already efficiently providing quality care. Those providers should not be penalized by achieving lesser savings. One possible solution could be linking shared savings to a national benchmark rather than the history of that population.

Section II.F.11. Net Sharing Rate
We would be supportive of first dollar savings after achieving the minimum savings rate. Eliminate the net savings threshold.

Section II.F.13. Withholding Performance Payments to Offset Future Losses
We oppose the 25% withhold. As discussed previously, ACOs will have to commit significant resources to create and maintain an ACO. If their efforts are successful, they should be paid all of their earned shared savings as a way to cover expenses and continue to invest in the ACO.

Section II.G.3.e. Ensuring ACO Repayment of Shared Losses
As discussed previously, we oppose holding ACOs responsible for shared losses. We similarly oppose requiring ACOs to establish a self-executing method for repaying losses, particularly as it may be imposed on individual providers. This is a particular concern for physicians who may not have a choice of whether to join an ACO based on their relationship with a hospital or health system. For physicians who are forced to participate, the ACO should not be able to require them to share in the losses.

Section II.G.3.h. Impact on States
In a recent meeting, regulators from the Indiana Department of Insurance told our Association that they did not believe these Proposed Rules implicated any State insurance laws.

Section II.H. Monitoring and Termination of ACOs
The proposed requirement to maintain ACO records exceeds our state law. Indiana does not have any statutory record retention requirement for business records and state law requires health records to be maintained for 7 years.

Section II.H.4. Reconsideration Review Process
We are concerned about the significant number of program determinations that are not subject to review. This is very harsh, particularly given the newness of this program.

Section II.I. Coordination with Other Agencies
Despite the policy statements issued by the other agencies on this Program, we continue to have concerns about potential fraud and abuse liability related to ACO formation and capitalization and antitrust liability. Providers are not likely to participate until these fears are alleviated.

Finally, the Indiana State Medical Association notes the uncertainty faced by entities who do wish to form or participate in an ACO. The delays in publishing the proposed rule, the presumed changes CMS will make in response to the approximately 116 requests for comment included in the proposed rule commentary, the time it will take for a final rule to be issued, and the preparation and application steps will render it an impossibility to roll out an ACO by January 1, 2012.

Thank you for your consideration of our comments.

Yours very truly,

Brent Mohr, M.D.
President