American Hospital Association

Liberty Place, Suite 700
325 Seventh Street, NW
Washington, DC 20004-2802
(202) 638-1100 Phone
www.aha.org

June 1, 2011

Donald M. Berwick, M.D., M.P.P.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations

Dear Dr. Berwick:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations and the nearly 200,000 employed physicians within those organizations, the American Hospital Association (AHA) is pleased to offer comments in response to the Centers for Medicare & Medicaid Services' (CMS) proposed regulation on Accountable Care Organizations (ACOs), as described in Section 3022 of the *Patient Protection and Affordable Care Act* (ACA), which establishes the Medicare Shared Savings Program.

The AHA has engaged in significant outreach to obtain input from our members and others on the proposed regulation. We have sought advice from policy experts on delivery reform, those working on establishing ACOs in the private sector, and the participants in the Physician Group Practice (PGP) demonstration. We have held several conference calls, webcasts and educational sessions to obtain feedback from our members. Finally, we have sought input from our governing bodies, including the AHA Board of Trustees, our nine Regional Policy Boards and our Governing Councils and Committees. All told, more than 800 hospital and health system leaders offered their thoughts to help formulate our comments on this proposed regulation.

Two central themes emerged throughout our conversations with members:

- First, hospital and health system leaders understand that they will need to provide patient care in a more accountable, more coordinated way and that they will be held increasingly at financial risk in improving outcomes for patients and becoming more efficient in the delivery of services. Many of our members are transforming care delivery to provide more "accountable care," whether they choose to enter into an agreement within the structure of the Medicare Shared Savings Program's ACOs or through some other model.

- Second, hospitals and health systems have responded to incentives established by public and private payers. They have built care processes and policies around the current regulatory structure of payment and delivery systems, and these systems will have to be changed if hospitals and health systems are to improve patient care and quality while reducing health care costs.

Since the enactment of the ACA, our members have been very excited about the prospect of the ACO program and eagerly anticipated CMS' proposed regulation. Many of our hospitals and health systems have engaged in "ACO-like" efforts to improve how care is delivered, often with private payers and employers, demonstrating that they are committed to the concept of accountable care. However, since the release of the proposed regulation, excitement about Medicare ACOs has dwindled dramatically. Many of our members are disappointed with the design of the ACO program as proposed. Substantial changes are needed to make the program operationally viable and attractive to potential participants.

The AHA recognizes that in crafting the proposed regulation, CMS attempted to achieve a balance between offering incentives for providers to participate in the ACO program and fulfilling CMS' obligation to protect taxpayers and the Medicare Trust Fund. However, as proposed, this balance is misaligned. The proposed rule places too much risk and burden on providers with little opportunity for reward in the form of shared savings, especially in light of the significant start-up and operating costs that providers must bear with little or no assistance. In order for hospitals to participate in the program in a meaningful way, a more appropriate balance is needed.

While we have commented under separate cover about the legal notices referred to later, this letter provides comments on the CMS' proposed rule on ACOs. Our comments are organized around the need for payment changes, operational flexibility, and quality measurement. We have not detailed every single concern we have with the proposed rule in our comment letter. Rather, we have chosen to focus on our main concerns—those that will need to be addressed to make the program attractive to potential participants and operationally viable.

RECOMMENDATIONS

To restore balance to the risk versus reward equation, we ask CMS to consider the following changes, which are discussed in detail in the attachment to this letter.

For the shared savings determination, we urge CMS to:

- eliminate down-side risk from the third year of Track 1, making it identical to the second year of Track 1;
- allow all ACOs to share in first-dollar savings once the "minimum savings rate" (MSR) is exceeded, no matter what track an ACO chooses;
- create a minimum sharing rate of 50 percent for Track 1 and 60 percent for Track 2, as well as use an ACO's quality score to award additional shared savings up to a maximum sharing rate of 80 percent for Track 1 and 90 percent for Track 2;
- hold all ACOs to a standard MSR of 1 or 2 percent, regardless of the track or number of attributed beneficiaries;

- eliminate the 25 percent withhold of all shared savings bonuses;
- standardize both the benchmark and performance year expenditures for all policy adjustments so that they reflect only actual resource utilization;

- remove all other non-resource use adjustments, such as direct graduate medical education and low-cost county payments, from the benchmark and performance year expenditure calculations;
- reconsider its methodology and propose adjustments for calculating the benchmark for each ACO so as not to disadvantage potential applicants in low-spending areas;
- give further consideration to additional ways to encourage participation of small and rural ACOs;
- consider providing up-front capital to engage small and/or rural ACOs; and
- apply the hierarchical condition codes (HCCs) risk adjustment annually to re-base the benchmarks for the severity of the ACO's population during each year of the program.

In addition, the AHA strongly urges CMS to assign beneficiaries prospectively to an ACO, as proposed in the Pioneer ACO model, to calculate eligibility for shared savings for a performance year. Program success will depend upon the ability of ACOs to manage their patients as effectively as possible. CMS' proposal for patient attribution presents a significant barrier to achieving this goal. CMS also should reconsider its definition of primary care and include specialists identified by the ACO or those included in the Pioneer ACO model in the definition of primary care.

CMS has proposed several requirements that restrict ACO operations. To allow ACOs the operational flexibility that will contribute to success, we suggest six changes:

- moderate its proposed governance requirements to allow providers to use their current governance process rather than require a separate entity and governing body for ACOs, as long as they can demonstrate how they achieve shared governance on care delivery policies;
- allow ACOs to add participants more frequently;
- reconsider the requirements for prior approval of all ACO communications with beneficiaries that are related to ACO operations or functions, as well as marketing activities, and address this issue in the context of issuing guidelines on the required notification of beneficiaries regarding the provider's participation in the ACO program;
- reconsider the meaningful use requirements proposed in the ACO regulation;
- do not specify a percentage-based meaningful use requirement for hospitals; and
- allow for a flexible start for participation in calendar year 2012.

ACOs are subject to significant performance risk in the form of quality measures tied to the shared savings bonus. In order to effectively manage the population through quality measures, we ask for the following changes:

- look to existing quality reporting programs and apply lessons learned from these efforts to the ACO program;

- reduce the large number of 65 proposed quality measures, adopt a smaller, concise measure set in the beginning of the program and increase the number of measures over time; and
- focus on measuring components of quality that are core to the goals of the ACO program.

Perhaps the biggest disappointment associated with the proposed ACO program is the continued barriers to clinical integration. As you know, the AHA has been vigorously requesting relief of several key legal barriers but these issues have not been addressed in a way that guarantees providers will be protected from the compliance risks associated with antitrust, Stark, anti-kickback, fraud and abuse, and other regulations. We appreciate CMS' recognition that current laws create barriers to the care coordination necessary to achieve the goals of the ACO program.

We welcome your willingness to break from the traditional enforcement silos and work collaboratively with four other agencies—the HHS Office of the Inspector General (OIG), the Department of Justice (DOJ), the Federal Trade Commission (FTC) and the Internal Revenue Service (IRS)—to coordinate the proposed regulation and notices on ACOs. CMS' collaboration with other agencies and departments is a necessary first step in beginning the process of removing the substantial legal and regulatory barriers to clinical integration.

Unfortunately, the resulting proposed changes and clarifications presented in the CMS/OIG notice and the FTC/DOJ policy fall far short of what is needed. Simply put, even if significant changes were made to the ACO program rules as discussed in this letter, we fear that these major barriers to clinical integration will impede the robust response to the ACO program that is desired by us all. We urge CMS to continue to work with the other federal agencies to resolve our concerns and refer you to the recommendations in our separate responses to the CMS/OIG and FTC/DOJ companion notices.

The AHA strongly supports the goals and principles that support the ACO program and delivery system reforms that improve patient care and quality while reducing costs. However, substantial changes are needed to make the program attractive to potential participants and operationally viable. We appreciate your consideration of our recommendations. If you have any questions, please contact me or Lisa Grabert, senior associate director of policy, at (202) 626-2305 or lgrabert@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President

cc: Jonathan D. Blum
Deputy Administrator and Director, Center for Medicare

Richard Gilfillan, M.D.
Acting Director, Center for Medicare and Medicaid Innovation

Terri Postma, M.D.
Medical Officer, Centers for Medicare & Medicaid Services

American Hospital Association
Detailed Comments on the Medicare Shared Savings Program: Accountable Care Organizations Proposed Rule

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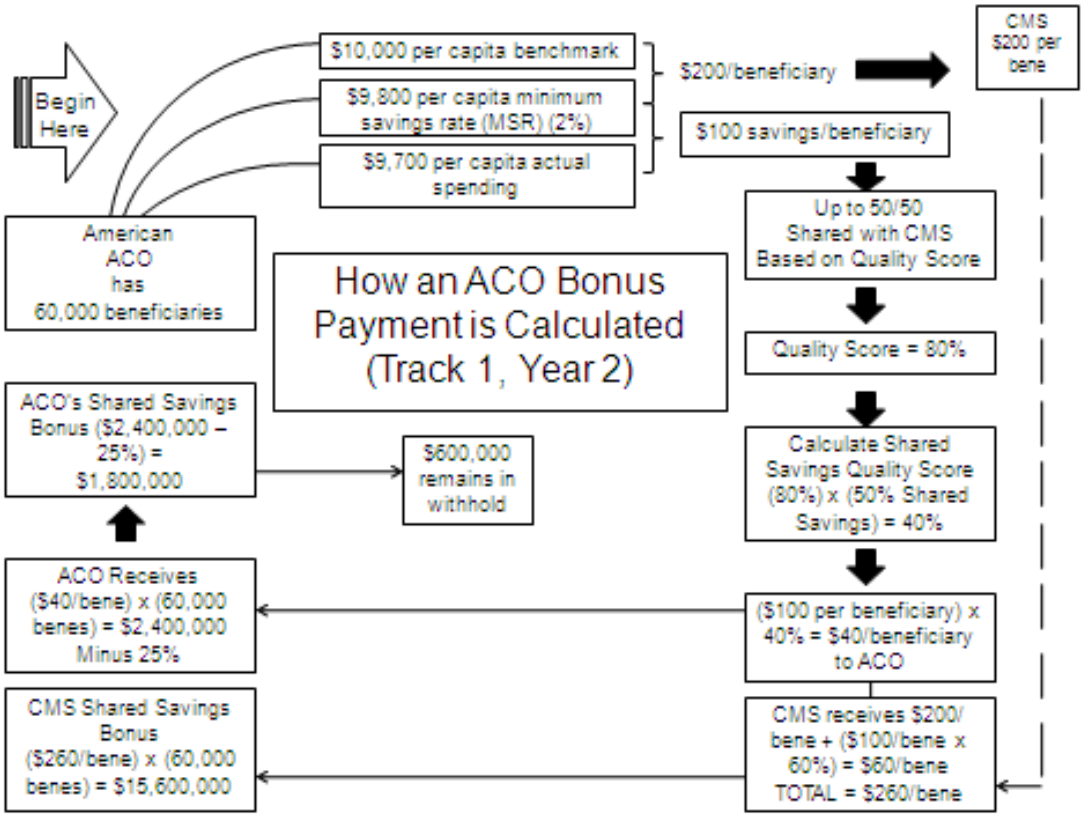
SHARED SAVINGS DETERMINATION

One of the AHA's major concerns with CMS' proposed rule for the ACO program is the imbalance in the shared savings determination. The risks ACOs are required to assume vastly outweigh the potential reward available. This is not a result of any one proposal in the rule, but rather the combination of all the payment-related proposals taken together.

CMS' overall risk versus reward equation tilts too much toward risk and too little toward reward. In the rule, CMS proposes that under the Track 1 one-sided risk model, it would share a maximum of 50 percent of the savings with the ACO. However, Figure 1 below illustrates that once all of the payment-related proposals are applied, an ACO would not receive anywhere near 50 percent of the savings. In this example, the hypothetical "American ACO" has 60,000 Medicare beneficiaries and saves $300 per beneficiary, or $18 million in total. Of the $18 million saved, CMS would keep $15.6 million or 87 percent, and the ACO would receive $2.4 million, or 13 percent. This 13 percent is then subject to a 25 percent withhold, which the ACO would not receive until the end of its three-year agreement with CMS. Thus, in reality, CMS would share much less than 50 percent of the savings with the ACO. Given the start-up and ongoing annual operational costs, which we discuss further in the regulatory impact analysis section below, as well as other program features for which ACOs carry all of the risk, this distribution of savings is extremely unattractive to potential program participants.

Figure 1: Example of Proposed Shared Savings Determination in Track 1, Year 2



The AHA offers several recommendations below to help bring the risk/reward equation into balance:

- Remove down-side risk from the third year of Track 1, making it identical to the second year of Track 1;
- Allow all ACOs to share in first-dollar savings once the "minimum savings rate" (MSR) is exceeded, no matter what track an ACO chooses;
- Create a minimum sharing rate of 50 percent for Track 1 and 60 percent for Track 2, as well as use an ACO's quality score to award additional shared savings up to a maximum sharing rate of 80 percent for Track 1 and 90 percent for Track 2;
- Hold all ACOs to a standard "minimum savings rate" (MSR) of one or two percent, regardless of the track or number of attributed beneficiaries;
- Eliminate the 25 percent withhold of all shared savings bonuses;
- Standardize both the benchmark and performance year expenditures for all policy adjustments so that they reflect only actual resource utilization.
- Remove all other non-resource use adjustments, such as direct graduate medical education and low-cost county payments, from the benchmark and performance year expenditure calculations;
- Reconsider its methodology and propose adjustments for calculating the benchmark for each ACO so as not to disadvantage potential applicants in low-spending areas;
- Give further consideration to additional ways to encourage participation of small and rural ACOs;
- Consider providing up-front capital to engage small and/or rural ACOs; and
- Apply the HCC risk adjustment annually to re-base the benchmarks for the severity of the ACO's population during each year of the program.

Down-side Risk under Track 1. **We urge CMS to eliminate down-side risk from the third year of Track 1, making it identical to the second-year of Track 1.** The Track 1 one-sided risk model is intended for entities less experienced with risk and, as such, does not hold ACOs accountable for down-side risk in the first two years of the required three-year agreement period. However, in the third-year of Track 1, CMS proposes that ACOs would be responsible for down-side risk in the form of losses. At this stage, the ACO is an untested, experimental model. It will take time, investment and hard work to bring a potential ACO to the point where it is operationally viable and poised to share in savings. The design of the ACO program should provide ample time for the less-experienced participants to fully organize themselves into an effective ACO structure. Though we understand CMS' eagerness to test alternative payment models, it already proposes to test a down-side risk model through Track 2, the two-sided risk model. The proposed rule should offer a shared savings option without any down-side risk, as was offered in the Physician Group Practice (PGP) demonstration and was contemplated by the statute.

In addition, another option would be to extend the agreement period to five or six years, with the adoption of down-side risk in the fifth or sixth year of the agreement. We also urge CMS to test additional payment models, such as partial capitation, as that model allows for down-side risk while also providing up-front capital to off-set the investment required to form an ACO.

First-dollar Savings. **We urge CMS to allow all ACOs to share in first-dollar savings once the MSR is exceeded, no matter what track an ACO chooses.** As currently proposed, ACOs may generally only share in first-dollar savings in the third year of Track 1 and in Track 2. Allowing first-dollar savings for all ACOs would help achieve more balance in the shared savings determination and make the program more attractive to participants.

Sharing Rate. **We urge CMS to create a minimum sharing rate of 50 percent for Track 1 and 60 percent for Track 2, as well as use an ACO's quality score to award additional shared savings up to a maximum sharing rate of 80 percent for Track 1 and 90 percent for Track 2.** As proposed, Track 1 ACOs would have a maximum shared savings rate of 50 percent and Track 2 ACOs a maximum shared savings rate of 60 percent. However, the manner in which CMS proposes to use the ACO's quality score to reduce the sharing rates makes these maximums unattainable. This is because unless an ACO scores 100 percent on all 65 proposed quality measures, which may not be possible, the quality score will always serve to reduce the sharing rate from the stated 50 and 60 percent. Thus, the current sharing rate is a ceiling; we urge CMS to modify the shared savings methodology to make the currently proposed sharing rates floors upon which quality scores can be used to award additional sharing points.

At the beginning of the PGP demonstration, CMS awarded 80 percent of the bonus to participants. Since PGP demonstration participants were not subject to down-side risk, this 80 percent number should serve as the basis for the Track 1 sharing rates. We feel, as does CMS, that ACOs that are required to take on down-side risk should have extra incentives. Thus, the maximum sharing rate should be increased to 90 percent for Track 2. Doing so would help achieve more balance in the shared savings distribution and, thus, make the program attractive to participants.

A higher sharing rate for providers is needed because the benchmarks would be rebased at the beginning of the second three-year agreement period (year four), meaning that CMS gets to keep 100 percent of the savings achieved over the first three-year period when an ACO's contract is renewed. Further, in the initial three-year period the small number of providers that will likely participate means that the overall risk to the Medicare program is minimal. However, from the perspective of participating providers, the Medicare population likely represents a third or more of their revenue base. This makes taking on an ACO arrangement a much riskier venture for ACOs than it is for CMS.

Minimum Savings Rate (MSR). **We urge CMS to hold all ACOs to a standard MSR of one or two percent, regardless of the track or number of attributed beneficiaries.** Based on our conversations with hospitals that are interested in forming ACOs, we believe that CMS must lower the MSRs, particularly if it aims to encourage participation of small and/or rural ACOs. A 2 percent MSR for all ACOs, which was used for the PGP demonstration, would still allow CMS to meet its statutory requirement to account for random variation.

The MSR is estimated by CMS so that an ACO with average expenditures and a given number of beneficiaries would be unlikely to achieve a shared savings payment by random chance alone. As proposed, in Track 1 the MSR would be set using a sliding scale based on the number of assigned beneficiaries. CMS proposes to set the MSR for an ACO with the minimum 5,000

assigned beneficiaries at 3.9 percent, based on a confidence interval of 90 percent. An ACO with 50,000 or more assigned beneficiaries would have a MSR of 2.2 percent, based on a confidence interval of 99 percent. As proposed, in Track 2, an ACO's MSR is fixed at 2 percent, no matter the number of assigned beneficiaries. The agency states that it believes a fixed MSR is appropriate for Track 2 because it provides greater predictability and is more likely to attract organizations to participate, and the Medicare Trust Fund is already protected because ACOs must share in any losses.

However, the manner in which the MSRs are proposed provides strong disincentives for an eligible entity to participate, particularly for smaller potential ACOs. For example, if the ACO in Figure 1 above had only 5,000 beneficiaries, it would have an MSR of 3.9 percent instead of 2 percent, and would not have received any shared savings at all. CMS would have kept the entire $300 per beneficiary that the ACO saved. Thus, the difference between earning a shared savings bonus or not can depend solely on an ACO's size, and not on the level of savings achieved. Though we understand that CMS would like to provide additional incentives for ACOs to participate in Track 2, the proposed MSRs in Track 1 serve to discourage participation.

In addition, while CMS proposes to use a sliding scale MSR for Track 1 based on the number of assigned beneficiaries, it artificially stops the sliding scale at 2 percent for the largest ACOs. If the agency will not implement a standard MSR for all ACOs in Track 1, then we urge it to not artificially stop the sliding scale at 2 percent, a number that has no empirical basis.

Shared Savings Withhold. **We urge CMS to eliminate the 25 percent withhold of all shared savings bonuses.** As proposed, CMS would use this withhold to offset any potential losses an ACO incurs or to motivate an ACO to fulfill its three-year commitment. Then, at the end of the three-year agreement period, the agency would return to the ACO any remaining withheld payments. However, extensive up-front investments and annual operating costs are required to become an ACO, as detailed in the regulatory impact section below. This large withhold robs ACOs of capital they need to continue to build their capacities and maintain their ACO structure. At the very least, CMS should pay interest on these withheld funds to ACOs.

Technical Adjustments to the Benchmark. **The AHA urges CMS to standardize both the benchmark and performance year expenditures for all policy adjustments so that they reflect only actual resource utilization. In addition, we urge CMS to remove all other non-resource use adjustments, such as direct graduate medical education and low-cost county payments, from the benchmark and performance year expenditure calculations.** CMS has proposed a literal interpretation of the statute, which requires CMS to adjust the annual expenditure benchmark for beneficiary characteristics and other factors, but only specifies that CMS adjust the annual performance year expenditures for beneficiary characteristics. Therefore, the agency proposes to include payment adjustments, such as indirect medical education (IME), disproportionate share hospital (DSH), hospital area wage index (AWI), geographic practice cost index (GPCI), hospital value-based purchasing (VBP) and meaningful use (for hospitals and critical access hospitals) in both the benchmark and performance expenditures so as not to distort comparisons between the two. However, the level of these adjustments and their change from year-to-year is beyond the control of individual providers and subject to substantial uncertainty in today's political environment.

We believe that CMS is looking at this issue too narrowly. Section 1899(i) of the ACA permits the Secretary, if determined to be appropriate, to use *any* payment models that are determined to improve the quality and efficiency of items and services furnished under the Medicare program.

CMS correctly recognizes that this authority extends to: (1) establishing alternative risk models different from the one described in section 1899(d); (2) selecting an update factor for the benchmark that may be different from the one implied by section 1899(d)(1)(B)(ii); and (3) utilizing a formula for determining the net sharing rate that ACOs may receive under a one-sided risk model that may be different from the one described in section 1899(d)(2). Establishing formulas other than those described in sections 1899(d)(1)(B)(i) and (ii) for calculating the benchmark and performance year actual expenditures is analogous to the types of alternative structures and calculations for which CMS recognizes authority under section 1899(i) and falls squarely within that authority.

These types of payments would have a significant impact on a potential ACO's benchmark and performance year expenditures. For example, almost one-quarter of prospective payment system (PPS) hospitals received in excess of $5 million in IME and DSH payments in fiscal year (FY) 2011. For about 20 percent of PPS hospitals, IME and DSH payments account for at least 20 percent of their Medicare inpatient hospital payments. Given that inpatient hospital payments account for about 40 percent of total Medicare payments, including high-IME and DSH hospitals in an ACO could increase that ACO's performance year expenditures by 8 percent or more. This could easily be the difference between earning a bonus, not earning a bonus, and incurring a loss. Thus, as proposed, the ACO program provides a strong disincentive to use high-IME and DSH hospitals, the hospitals that train our nation's future physicians and disproportionately serve as the safety net of health care in America. We should encourage these types of hospitals to be included in ACOs.

CMS also proposes to include hospital AWI and physician GPCI payments in both the benchmark and performance year expenditures. However, these payments are extremely volatile from year-to- year not only in and of themselves, but also because of external policy actions. For example, the wage indices of about 8 percent of core-based statistical areas changed by at least 5 percent in FY 2011 compared to FY 2010. These large changes are simply due to the routine annual recalculation of the area wage index.

In addition, the wage indices of about 6 percent of individual PPS hospitals changed by at least 5 percent in FY 2011 compared to FY 2010. These large changes are due to a multitude of factors. For example, they can reflect either the loss or gain of a regulatory reclassification, such as through the Medicare Geographic Classification Review Board. They also can reflect the beginning or end of statutorily mandated policies, such as the frontier wage index policy that began in FY 2011. Thus, including geographic adjustments like the AWI and the GPCIs in the benchmark and performance year expenditure calculations will introduce volatility into the program and could cause an ACO to either earn or lose a bonus payment, not because of its own actions, but because of policy or market factors outside of its control.

Finally, including payments such as VBP and meaningful use bonuses in the benchmark and performance year expenditures introduces conflicting incentives into the Medicare program. On

the one hand, under the VBP program for example, CMS provides hospitals with incentives to improve the quality and safety of the care they provide to patients; hospitals will strive to do well on their quality measures to obtain a high VBP score bonus. On the other hand, the proposed ACO policy provides a strong disincentive to use such high-performing hospitals because their use could increase an ACO's performance year expenditures and easily be the difference between earning a bonus, not earning a bonus, and incurring a loss. The same point is applicable to meaningful use bonuses.

We also urge CMS to reconsider its methodology and propose adjustments for calculating the benchmark for each ACO so as not to disadvantage potential applicants in low-spending areas. The ACA requires the Secretary to establish a benchmark for each ACO based on the most recent three years of Medicare parts A and B per beneficiary expenditures. According to the proposed rule, the benchmark, to be calculated at the beginning of each three-year agreement, would then be updated by the projected absolute amount of growth in national per capita expenditures. CMS believes that the proposed approach will provide appropriate incentives to form ACOs in both high spending/high growth and low-spending/low growth areas. The AHA is concerned that this proposed approach will dissuade potential participants in low-spending areas from applying to the shared savings program. We urge CMS to conduct an analysis of this issue and propose appropriate adjustments.

Finally, we ask CMS to provide for exemptions for natural disasters and other emergency situations that might affect the utilization of health care resources or ACO operations in a region, as the agency does for other programs. Such exemptions also should include mechanisms to adjust benchmarks for disaster-related health care needs.

Small or Rural ACOs. **We urge CMS to give further consideration to additional ways to encourage participation of small and rural ACOs.** Two of our recommendations above would help do so—implementing a flat one to two percent MSR for all ACOs and allowing all ACOs to share in first-dollar savings. Although the agency already proposes to allow certain small ACOs to share in first-dollar savings, these exceptions are written much too narrowly and would apply to few, if any, potential ACOs.

In addition, we encourage CMS to consider providing up-front capital to engage small and/or rural ACOs. One potential mechanism for offering assistance is through the Center for Medicare and Medicaid Innovation (CMMI), and we commend CMS and the CMMI for its proposal to advance monthly shared savings payments. We urge CMS to provide up-front investments outside of the shared savings bonus, in addition to those associated with shared savings.

We also urge CMS to expand the definition of primary care to include nurse practitioners (NPs) and physician assistants (PAs). Small and/or rural providers have identified CMS' proposed definition of primary care as a concern, since they often rely on NPs and PAs to provide primary care; however, we recognize this is a statutory requirement.

Risk adjustment. **We urge CMS to apply the hierarchical condition codes (HCC) risk adjustment annually to re-base the benchmarks for the severity of the ACO's population**

during each year of the program. CMS proposes to establish benchmarks for the first year of the agreement period using the parts A and B fee-for-service (FFS) expenditures of beneficiaries *who would have been* assigned to an ACO in the three years prior to the agreement period. The agency proposes to adjust the benchmark for beneficiary health status using the CMS HCC adjustments that are used in the Medicare Advantage program. Once CMS adjusts the baseline population using the HCCs, it does not intend to make any additional adjustments for population risk in the three-year agreement period even though the risk profile of the population ultimately assigned to the ACO could be quite different from that used to set the benchmarks, if the population is older and sicker.

However, CMS is required, by law, to adjust the expenditure benchmark each year for beneficiary characteristics. Specifically, the ACA requires that an adjustment be made on an annual basis to account for the difference between such estimated average per capita Medicare expenditures in a year, adjusted for beneficiary characteristics.

REGULATORY IMPACT ANALYSIS

Investment. The discrepancy between the investment required and the potential for reward imposes significant business risk for an ACO. Becoming an ACO requires a substantial investment. CMS estimated it will cost approximately $1.8 million to form an ACO and operate in the first year. This estimate is based on an assessment of the Physician Group Practice (PGP) demonstration project sites, which at the time of entry into the demonstration were already highly integrated, supported by electronic health records, and experienced in managing care across the continuum.

However, at the direction of the AHA, McManis Consulting recently completed four case studies to assess the capabilities required to be successful as an ACO and the associated costs. These four case studies vary in size and organization type, including a large health system, a physician-only group practice, a single hospital community system and an independent practice association affiliated with a hospital system. Additional information on each of the case studies is available at www.aha.org/ACOcasestudies. These four case study sites reside in four distinct geographic areas and represent different models for ACO development. McManis Consulting identified 23 activities and costs related to establishing an "ACO-like" organization (see Attachment A).

These case studies provide the supporting research for a report documenting the costs of becoming an ACO, which we have made publicly available.[1] **Estimates by McManis Consulting have determined the combined start-up and first-year ongoing costs are much higher than CMS estimated. Specifically, for a small ACO, costs were estimated to be $11.6 million and for a medium ACO to be $26.1 million.**

[1] www.aha.org/ACOcasestudies

Table 1: Estimates of ACO Start-up and Ongoing Costs for Year 1

Estimate of ACO Investment	Average
CMS (based on a range of 75 to 150 ACOs)	$1,800,000
McManis (200-bed, single hospital system with 80 primary care physicians and 150 specialists)	$11,600,000
McManis (1200-bed, 5-hospital system with 250 primary care physicians and 500 specialists)	$26,100,000

Note: McManis's estimates are based on case studies and include start-up and on-going costs for a typical year. Some costs may have already been incurred or be allocable to other budgets.

We recommend that CMS consider the regulatory costs of ACO operations in deciding payment issues. Although the ACA exempted CMS from the Executive Order 12866 requirement to prepare a regulatory impact analysis (RIA) for the proposed ACO regulation, the AHA was able to use RIAs previously developed by CMS for other programs—including the Electronic Health Records program and the Medicare Advantage quality reporting program—to develop the above burden estimates for select program requirements (see Attachment B).

Using CMS RIA burden estimates, the AHA extrapolated the costs of the ACO requirement by applying the appropriate program parameters. For example, CMS estimated it would cost $4,582 ($58 per hour x 79 hours per group practice) per physician group to participate in the Physician Quality Reporting System Group Practice Reporting Option (GPRO). However, the RIA is for reporting only three measures and the ACO rule requires reporting of 46 measures. To develop our estimate we used the following calculation: ($4582) / (3) * (46) and arrived at the $70,257 estimated impact of using a GPRO-like tool to report 46 quality measures. The table in Attachment B provides links to the CMS RIAs used to develop each estimate.

ASSIGNMENT OF MEDICARE FFS BENEFICIARIES

We urge CMS to assign beneficiaries prospectively as CMS has proposed in the Pioneer ACO model. As proposed, CMS would retrospectively assign beneficiaries to an ACO for purposes of determining shared savings. Thus, the ACO would not be able to identify its attributed beneficiaries in real time. In fact, it would be more than six months after the performance year ended until they could identify their attributed beneficiaries. While the hospital field firmly shares CMS' goal of improving care coordination for all patients, retrospective assignment is the wrong approach. To take responsibility for the health of a population in both the fiscal and quality arenas, it is essential to understand the population for which the ACO is accountable. Providers cannot do this unless they can identify the assigned population upfront. They would then be able to effectively target the population, identify high-risk individuals, develop specific outreach programs, and proactively work with patients and their families to establish care plans.

As CMS notes in the proposed regulation, if it were to assign beneficiaries prospectively, it would likely still need to complete a retrospective reconciliation on an annual basis. We agree with CMS' assessment and encourage CMS to allow for a reconciliation of assigned beneficiaries at the end of the measurement year to account for changing care patterns, such as

beneficiaries transitioning into a Medicare Advantage Program or beneficiaries who receive a significant portion of their care well outside of an ACO's primary service area.

In addition, we urge CMS to reconsider its definition of primary care and include specialists identified by the ACO or those included in the Pioneer ACO model in the definition of primary care. One additional barrier that several AHA members have identified within CMS' attribution proposals is the limited, narrow definition of primary care that CMS intends to use for beneficiary attribution. In many institutions, providers other than the specialties of family practice, internal medicine, geriatrics, and general practice are the primary care managers for patients with chronic conditions. ACOs should be allowed to identify professionals as primary care providers regardless of specialty.

ADDITIONAL OPERATIONAL CONCERNS

CMS has proposed several requirements that restrict ACO operations, discussed below, that could inhibit program success. We provide six recommendations that allow for greater flexibility:

- moderate proposed governance requirements to allow providers to use their current governance process rather than require a separate entity and governing body for ACOs, as long as they can demonstrate how they achieve shared governance on care delivery policies;
- allow ACOs to add participants more frequently;
- reconsider the requirements for prior approval of all ACO communications with beneficiaries that are related to ACO operations or functions, as well as marketing activities, and address this issue in the context of issuing guidelines on the required notification of beneficiaries regarding the provider's participation in the ACO program;
- reconsider the meaningful use requirements proposed in the ACO regulation;
- do not specify a percentage-based meaningful use requirement for hospitals; and
- allow for a flexible start for participation in calendar year 2012.

ELIGIBILITY AND GOVERNANCE

Governance. **We urge CMS to moderate its proposed governance requirements to allow providers to use their current governance process rather than require a separate entity and governing body for ACOs, as long as they can demonstrate how they achieve shared governance on care delivery policies.** Of particular concern are the governing body composition requirements. There are a host of factors to consider in selecting the number and type of governing body members for any given organization and each ACO needs the flexibility to address those considerations independently.

The level of prescription proposed by CMS is unnecessary and very limiting. CMS would require that at least 75 percent control (that is, voting rights) of the governing body be held by ACO participants; that control be proportionate for each participant; that each ACO participant

have at least one representative on the governing body, chosen by the ACO participant organization that he or she represents; and that at least one Medicare beneficiary served by the ACO be represented on the ACO's board.

If each ACO participant has at least one vote, the size of some governing bodies could be dysfunctional. Similarly, voting rights on governing bodies often need to reflect capital contributions to the entity and the concept of proportionality in voting rights is generally determined in the same way. These governance composition requirements are a key reason why many integrated delivery systems would have to bear the expense of establishing a separate legal entity with its own governing body. They do not allow an organization to leverage an existing governance structure.

If, as suggested by the discussion of the proposed composition requirements, CMS' intent was to ensure that ACO participants and providers have significant input and control over decisions about how care will be delivered and that the Medicare beneficiary's voice be heard as well, then the rules should simply require the ACO applicant to show how that will be accomplished. We believe rigid composition requirements are the wrong approach to ensure that the ACA's requirement for shared governance is met.

We urge CMS to review carefully and clarify the terms "eligible ACO participants," "ACO participants," and "ACO providers/suppliers" as used in the three related ACO rules to ensure that the terms used are adequately defined and appropriate to the context of the requirements. The AHA also believes that lack of consistency in the use of these terms makes it difficult to appropriately interpret the rules on board composition, as well as other elements of the proposal and those of the FTC/DOJ and CMS/OIG. It is clear that those providers/suppliers eligible to independently form an ACO are a limited group of the providers/suppliers who are also eligible to be ACO participants. However, the proposed regulation often refers simply to "ACO participants" when discussing a variety of requirements without being clear as to whether the requirement applies to the "formers" of the ACO or to the broader group of ACO participants. It is unclear whether use of the term "eligible ACO participants" (such as in the definition of an ACO) refers to those eligible to form an ACO (the short list) or those included in the definition of an ACO participant (all Medicare-certified providers and suppliers). An example is the section on the ACO agreement which requires that all ACO participants and providers/suppliers have a meaningful commitment to the ACO's clinical integration program in the form of financial or human investments (such as time and effort). It is unclear whether non-financial investments require a portion of control on the ACO governing body and, if so, how proportionality would be measured. What does seem clear is that the requirement for all ACO participants to have a meaningful commitment and stake in the ACO's clinical integration success is tied to the protections proposed under program integrity and antitrust policies.

Additional participants. **We urge CMS to allow ACOs to add participants more frequently.** In its proposal, CMS would not allow ACOs to add any participants, such as a group of physicians, to the organization during the course of the three-year agreement. Many of our members have explicitly identified this particular proposal as a barrier to ACO formation. It is fairly common for hospitals or other organizations to add a small group of physicians during the course of a year. At a minimum, CMS should consider relaxing this proposal to an annual

reconsideration. CMS intends to assign beneficiaries annually and ACOs should be afforded the same flexibility to add participants annually, for increased operational flexibility.

Marketing requirements. **We urge CMS to reconsider the requirements for prior approval of all ACO communications with beneficiaries that are related to ACO operations or functions, as well as marketing activities, and address this issue in the context of issuing guidelines on the required notification of beneficiaries regarding the provider's participation in the ACO program**. CMS' stated intent is to ensure that Medicare beneficiaries understand they have the right to choose among health care providers and settings. The agency is concerned that beneficiaries may be misled about what services they are allowed to receive, as well as the providers and suppliers that are allowed to deliver their services.

We believe CMS' concerns are misplaced because the ACO program does not involve marketing to Medicare beneficiaries, unlike the Medicare Advantage (MA) program where an alternative program is being marketed to beneficiaries and there has been a history of inappropriate marketing. We fail to see what opportunities or advantages would be gained by any marketing activities. Under the proposed ACO program, there is no enrollment and, as proposed, providers do not know which beneficiaries will be attributed to their ACO until the performance year is over.

Even if the program changed so that marketing were more relevant, the proposed prior approval requirement is overly burdensome and could cause delays in the ACO's required functions. The proposal goes far beyond the "file and use" approach employed under the MA program and most state insurance market conduct rules whereby an agency issues guidelines or model language for marketing materials—plans are required to follow them and submit their materials to the agency, but are allowed to use them after a short period (such as 30 days). In that way, the entity is not subject to significant delays. The agency still has the opportunity to review the materials and raise any issues during the review.

Meaningful use. **We urge CMS to reconsider the meaningful use requirements proposed in the ACO regulation**. CMS would require an ACO to have at least 50 percent of its primary care physicians become meaningful users for the Medicare or Medicaid Electronic Health Record (EHR) Incentives Programs by the start of the second ACO performance year. While we believe that health information technology (IT) will be an important enabler of ACO success, and ACOs will be investing in these technologies, the meaningful use criteria represent a very high bar for many providers. Whether a 50 percent adoption rate is realistic is uncertain given the current stage of implementation of the meaningful use program, but we expect that it is not. Attestation to meaningful use began only in April, and very few providers have successfully met the requirements so far.

Requiring a 50 percent rate would entail significant risk for ACOs being asked to make this commitment up front. In addition, a high threshold, absent evidence of trends in adoption of certified EHRs in stage 1 meaningful use, may hinder primary care provider participation in the ACO. The PGP participants have commented on the importance of their information systems and EHRs in managing the care of patients, although they were not using certified EHRs or meeting the specific meaningful use requirements. Among the learnings from the ACO program

will be the kinds of IT systems that are best suited for coordinating care and demonstrating accountability, which may be different from the meaningful use requirements.

An alternative approach would be for CMS to measure the estimated primary care provider use of EHRs at the time of the program launch as a baseline, require ACOs to track this information, and establish the expectation that a future threshold will be set and increase over the period of the ACO program. We support the direction in the proposed rule to not impose a requirement on providers within the ACO other than PCPs.

Additionally, we believe that CMS should not specify a percentage-based meaningful use requirement for hospitals. Few hospitals have been able to successfully meet meaningful use to date, and our members report rising costs, limited vendor capacity, and shortages of skilled technical and clinical IT staff as significant challenges. Further, given the complexities of introducing an EHR while also preparing for ICD-10, we believe different organizations have made rational and thoughtful decisions to stage implementation in different ways. Both EHRs and ICD-10 must move forward, but the order in which they occur may vary for logical reasons peculiar to each organization. It would be unfortunate to preclude those who have chosen to prepare for ICD-10 before implementing an EHR system from participating in this program while those who prioritized EHR implementation are allowed to move forward. In addition, studies have shown that small and rural hospitals have, on average, farther to go to meet the meaningful use requirements. Including a meaningful use requirement could have the unintended consequence of limiting their participation in the ACO program.

Operational ramp-up. **We urge CMS to allow for a flexible start for participation in calendar year 2012.** We recognize that the statutory start date of the shared savings program is January 1, 2012. However, given the release date of the ACO proposed regulation (March 31) and the time needed for CMS to address public comment, we anticipate that the final ACO regulation may not be released until the fourth quarter of 2011. This will not allow potential ACOs enough time to make a decision regarding participation, or complete the required complex application, in advance of CMS' proposed start date of January 1, 2012. Recognizing the timing issues, CMS also proposed an alternative start date of July 1, 2012. We also think the July 1 date may be too aggressive for the start date of the program. For example, if CMS finalizes all 65 quality measures, ACOs will need significant lead time to build the infrastructure to report those measures. However, if CMS finalizes far less than 65 measures, as we suggest later in this comment letter, ACOs may not need as much lead time. A flexible start would allow both CMS and potential ACOs a transition period during which some of uncertainties could be ironed out prior to beginning the fully operational program where ACOs are at risk.

QUALITY AND OTHER REPORTING REQUIREMENTS

The language in the ACA made clear that measuring quality of care is to be an integral part of the ACO program. The AHA has long supported quality reporting efforts and the transparency of hospital quality information, and we agree that ensuring quality of care under the ACO program is critical. We recognize that CMS has never measured quality of an entity such as an

ACO, and determining the appropriate quality measures and appropriate data collection mechanisms will require some creativity and flexibility.

In determining how to assess ACOs on quality, we urge CMS first and foremost to focus on measuring components of quality that are core to the goals of the ACO program. The ACA language states that the program should promote accountability for a patient population, coordinate the delivery of health care services, encourage investment in infrastructure, and redesign care processes for high quality and efficient service delivery. We believe these are the cornerstones of the ACO program, and they are where CMS should focus its quality measurement activities.

Initial Implementation. **We encourage CMS to look to existing quality reporting programs and apply lessons learned from these efforts to the ACO program**. In particular, the hospital quality reporting program can offer valuable insights into how a well-focused effort to collect data on high priority areas can drive extensive performance improvement.

CMS proposes to collect quality information from ACOs on 65 measures within five conceptual domains. Many of our members have commented that 65 measures, beginning in year one of the program, are too numerous and burdensome for a quality measure set. In contrast, the hospital quality reporting program, which in FY 2004 tied quality reporting to the hospital inpatient payment update, began with a starter set of 10 measures reflecting three clinical topics: heart attack, heart failure and pneumonia. A small number of new measures were added each year. After seven years of reporting quality measures to CMS, for FY 2011, hospitals now have to report 45 quality measures to receive a full market-basket update. The hospital inpatient quality reporting (IQR) program will form the basis for the hospital value-based purchasing (VBP) program beginning in FY 2013. For VBP, hospitals will report on 13 measures; for FY 2014, hospitals will report on an additional 13 measures (as stated so far), for a total of 26 measures.

The AHA suggests that CMS use a concise set of measures in the beginning of the ACO program. As new measures have been introduced, hospitals have focused on each new measure and increased quality improvement efforts in those areas. The results have been remarkable. Hospitals' overall performance has improved, sometimes rapidly, on every single measure added to the Medicare hospital quality reporting program. The national median score is now 90 percent or higher for most of the measures that are reported, and those hospitals with the lowest baseline scores at the introduction of a measure have improved the most. This system, which gradually introduced quality measures, has worked beyond expectations. The initial core measure set should consist of the most critical measures in key leverage areas. Then, as ACOs gain experience with their new responsibilities to be the entities accountable for the care provided to their members, it may be appropriate to add additional quality metrics. We note that the PGP demonstration began with eight measures, building to 32 by the end of the first phase of the demonstration.

Quality Performance Standards. As recommended above, **we urge CMS to use the currently proposed sharing rates of 50 and 60 percent as floors instead of ceilings**. ACOs should be eligible to earn sharing rates of up to 80 percent for Track 1 and 90 percent for Track 2 based on

their quality scores. Doing so would help achieve balance in the shared savings distribution and make the program attractive to potential participants.

If CMS does not accept our recommendation to set the sharing rate as a floor instead of a ceiling, CMS should require only reporting of quality measures for the first three years. Asking ACOs to submit quality measures, many of which may be reported for the first time, and then tying the performance on those measures to benchmarks unknown to anyone in the second year of the program is too aggressive. While performance should be measured against benchmarks, the ACO's sharing percentage should not be adjusted by performance until quality benchmarks can be provided prospectively so that ACO participants can identify current performance levels by measure and the expected target to receive the highest possible sharing levels.

Selection of Quality Measures. Keeping in mind the cornerstones of the ACO program—accountability, coordination of care, investment in infrastructure, and high-quality, efficient service delivery—and allowing the program to start with a focused, concise list of quality measures, we suggest the following quality measures be included in the ACO program.

Patient experiences with care – CG-CAHPS. **We support the use of the CG-CAHPS tool in the ACO program.** Assessing patient experiences with care provided through the ACO is an absolutely critical component to assessing ACO quality. We ask CMS to provide more clarification on what will be required of ACOs to report on this measure, such as detailing the number of beneficiaries that must be sampled for the survey and the timing around both the issuance of the survey and the when the results must be submitted to CMS.

Mortality. **Because mortality is the ultimate patient outcome, we encourage CMS to consider whether mortality data should be collected and reported as part of the quality measures for ACOs.** Currently, CMS uses 30-day post-admission measures of heart attack, heart failure and pneumonia to assess quality in the hospital setting. These will provide a starting point for mortality measurement within ACOs, and signal that CMS does intend to pay attention to changes in mortality rates to determine whether an ACO is improving quality. However, they fall short of what is needed to measure ACO performance for several reasons. For example, ACOs are intended to provide care for a population of individuals, many of whom may not be hospitalized during a year. To use only measures that begin when a patient is hospitalized would mean that CMS would be blind to mortality occurring outside the hospital setting and among those who are never hospitalized for any cause.

Additionally, we urge CMS to develop rapidly a risk-adjusted all cause mortality measure for all patients enrolled in the ACO to capture mortality on both those who are admitted to a hospital and those who are not. It will clearly be challenging to develop a sufficiently robust risk adjustment method for such a measure, but the investment in such a measure will be important as CMS assesses the success of this ACO initiative, as well as the Pioneer ACO initiative, the bundled payment initiatives, and some of the community based efforts being funded by CMS, the Centers for Diseases Control and Prevention (CDC), the Health Resources and Services Administration (HRSA) and others. In fact, some of CDC's efforts to compare and contrast the effectiveness of a variety of public health initiatives may provide extremely useful insights as CMS tries to construct a population-based mortality measure, and we would urge

CMS to work with the public health officials at CDC in conceptualizing and developing this measure.

Readmissions. **We urge CMS to change the readmission measure to be more specific to heart attack, heart failure, and pneumonia.** CMS proposes to include an all-cause risk-standardized readmission measure. The AHA fully supports efforts to reduce and measure readmission rates. However, our research has indicated that the causes of readmissions are complex and there are no shelf-ready solutions that can be applied globally to reduce all readmissions. We have found that concentrating on specific groups of patients with a common diagnosis, such as congestive heart failure, has yielded positive results. We urge CMS to invest in modifying these readmission measures so that they address only unplanned, related readmissions. We do not support including the all-cause, all-condition risk-standardized measure in the ACO program.

Care coordination. **We believe many of the measures CMS has proposed as care coordination measures are appropriate for the ACO program.** CMS would measure ACOs on seven ambulatory care sensitive admissions that would be calculated by CMS using Medicare claims data. These seven measures address conditions, that when managed properly in an ambulatory setting, should not result in an inpatient admission. Though these measures are not perfect and should be improved over time, they do address important gaps in care delivery that highlight areas of inefficiency. We support including these measures in the ACO program. These are very important quality measures to which ACOs will need timely access. We urge CMS to provide feedback on these measures to ACOs, at a minimum, on a monthly basis.

We believe that ensuring smooth transitions of care is one of the most critical actions that an ACO can take to improve patient care. Therefore, measuring ACOs' performance during care transitions is important. However, we believe there are better care transitions measures available than the ones proposed by CMS. We encourage CMS to include the care transition measures that have been developed by the American Medical Association's (AMA) Physician Consortium for Performance Improvement (PCPI). The AMA PCPI has developed three measures of care transitions. These measures assess whether the patient received a reconciled medication list upon discharge, whether a transition record with specified information was received by the discharged patient, and whether the transition record was transmitted in a timely manner.

Use of health information technology. The use of interoperable health information systems, including widespread use of EHRs is critical to effective ACO operations and seamless care transitions. CMS proposes five measures of health IT. We believe most of these measures are redundant and suggest instead that CMS simply ask ACOs to report on the percentage of primary care physicians who are meaningful users. Requiring additional measures of physician use of e-prescribing, clinical decision support tool, and registry use is redundant as all of these functions are part of the meaningful use requirements. As we stated earlier in this letter, we do not believe that CMS should specify a percentage-based meaningful use requirement for hospitals.

Population health/prevention measures. **CMS' proposal to include preventive health and population measures is appropriate.** However, given the reporting burden brought on by both the breadth of the measures proposed and redundancy within the measure set (e.g., assessing

ACOs on the proportion of their diabetes patients with hemoglobin A1c levels both below 8 percent and above 9 percent), we believe CMS should limit the number of measures that assess prevention and population health. Of the measures proposed, we suggest CMS re-evaluate the list and select the subset of measures for which the strongest evidence exists that following that particular care process results in improved patient outcomes. Only those measures with a very strong link to improved patient outcomes should be selected. Measures that assess "intermediate outcomes" often are stronger measures. For example, CMS could consider retaining the measure that assesses whether patients with coronary artery disease (CAD) actually have controlled low density lipoprotein (LDL) cholesterol levels and not include the measure that only assesses whether CAD patients have been directed to take medication to lower their cholesterol.

Patient safety measures. **We recommend that CMS expand its focus on patient safety to more broadly assess for any unintended adverse consequences that may be brought on by the financial incentives inherent in the ACO program which may promote the underuse of some needed services.** Patient safety is a critical component of care delivery. CMS would be wise to select measures that can assess whether patients have access to needed care, particularly costly services. Unfortunately, few quality measures address underuse. CMS could look at the length of patient wait time until a major surgery (which is one way of limiting access to care). Or, CMS could choose one or two costly services (e.g., MRIs, hip replacements, any of the solid organ transplant services, or cardiac valve replacements) where there are good existing guidelines around which patients benefit from the services, and develop measures to look at the proportion of patients meeting those criteria who get the service. If the percentage drops during the course of the demonstration, it should raise questions.

CMS proposes two measures of patient safety. The first measure is a large composite measure including hospital-acquired conditions (HAC), patient safety indicators (PSI) and two CDC infection measures. The second CMS measure proposed in this domain is the central-line blood stream infection (CLABSI) bundle. Unfortunately, these measures assess risks for hospitals, not the broader safety issues that are critical for a health care delivery system such as an ACO. While we are very concerned about including the HAC, PSI, and CDC infection measures in the ACO program, the CLABSI bundle could be included until better measures that span the ACO are developed.

Quality reporting timeframes. **We urge CMS, in the final ACO rule, to clearly articulate the reporting period, due date of submission, and the population that is being measured for each of the quality measures.** Many of the operational details needed to properly comment on the quality measures are missing from the proposed regulation.

Attachment A: ACO-like Activities and Costs

SUMMARY: ACTIVITIES AND COSTS TO ESTABLISH AN ACO-LIKE ORGANIZATION

	Prototype A: (200 bed, 1-hospital system 80 PCPs, 150 specialists)		Prototype B: (1,200 bed, 5-hospital system, 250 PCPs, 500 specialists)	
Activity	**Start up Costs**	**Ongoing (Annual) Costs**	**Start up Costs**	**Ongoing (Annual) Costs**
Group I. Network Development and Management				
1. Providing ACO management and staff	$550,000	$1,450,000	$600,000	$3,200,000
2. Leveraging the health system's management resources	$250,000	$200,000	$300,000	$250,000
3. Engaging legal and consulting support	$350,000	$125,000	$500,000	$125,000
4. Developing financial and management information support systems	$500,000	$80,000	$500,000	$160,000
5. Recruiting/acquiring primary care professionals, right-sizing practices	$400,000	$800,000	$800,000	1,600,000
6. Developing and managing relationships with specialists	*	*	*	*
7. Developing and managing an effective post-acute care network	*	*	*	*
8. Developing contracting capabilities	$150,000	$150,000	$150,000	$150,000
9. Compensating physician leaders	$75,000	$75,000	$190,000	$190,000
Group II. Care Coordination, Quality Improvement and Utilization Management				
10. Disease registries	$75,000	$10,000	$150,000	$20,000
11. Care coordination and discharge follow-up	$150,000	$1,000,000	$300,000	$3,000,000
12. Specialty-specific disease management	–	$150,000		$300,000
13. Hospitalists	$80,000	$160,000	$160,000	$320,000
14. Integration of inpatient and ambulatory approaches in service lines	*	*	*	*
15. Patient education and support	–	$100,000	–	$100,000
16. Medication management	–	$100,000	–	$100,000
17. Achieving designation as a patient-centered medical home	$100,000	$15,000	$150,000	$25,000
Group III. Clinical Information Systems				
18. Electronic health record (EHR)	$2,000,000	$1,200,000	$7,050,000	$3,500,000
19. Intra-system EHR interoperability (hospitals, medical practices, other)	$200,000	$200,000	$400,000	$200,000
20. Linking to a health information exchange (HIE)	$150,000	$100,000	$200,000	$200,000
Group IV. Data Analytics				
21. Analysis of care patterns	$210,000	$210,000	$450,000	$450,000
22. Quality reporting costs	$75,000	$75,000	$100,000	$100,000
23. Other activities and costs	–	$100,000	–	$100,000
TOTAL	**$5,315,000**	**$6,300,000**	**$12,000,000**	**$14,090,000**

**Costs are primarily management and staff and are included in previous elements (1,2 and 3).*

Attachment B: Burden Estimations

Proposed ACO Requirement	CMS Estimated Burden for Similar Regulatory Requirement	Estimated burden for ACO Requirement
Reporting of quality measures using GPRO 1-like tool	Physician Quality Reporting System, Physician Fee Schedule, 2011 http://edocket.access.gpo.gov/2010/pdf/2010-27969.pdf	$70,257
Reporting of patient experience measures	Final Medicare Advantage Rule, 2010 http://edocket.access.gpo.gov/2010/pdf/2010-7966.pdf	$118,000
Reporting of care transition measure	Final Medicare Advantage Rule, 2010 http://edocket.access.gpo.gov/2010/pdf/2010-7966.pdf	$59,000
Achieving meaningful use	Final Meaningful Use Rule, 2010 http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf	$1.9 million
Maintaining meaningful use	Final Meaningful Use Rule , 2010 http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf	$360,000
CMS approval of all marketing materials	Final Medicare Advantage Rule, 2005 http://edocket.access.gpo.gov/2005/pdf/05-1322.pdf	$708
Patient notification and consent	Proposed Rule on Patient Notification of Right to Access Quality Improvement Organizations, 2011 http://www.gpo.gov/fdsys/pkg/FR-2011-02-02/pdf/2011-2275.pdf	$78,000 for 1.4 million beneficiaries and 75 ACOs $111,000 for 4 million beneficiaries and 150 ACOs