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Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Shared Savings Program: Accountable Care Organizations (CMS–1345–P)

On behalf of the American Heart Association (AHA), its American Stroke Association (ASA) division and over 22 million AHA and ASA volunteers and supporters, we appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) notice of proposed rule-making (NPRM) for the Medicare Shared Savings Program (MSSP).

The AHA is dedicated to building healthier lives, reducing death and disability from cardiovascular diseases (CVD) and stroke, and addressing issues of access, quality, and cost from the patient's perspective. Although the United States has been successful in reducing death rates for coronary heart disease and stroke - the #1 and #3 leading causes of death in the United States - much work remains to address these leading causes of death and disability. Among other issues, the fragmentation of services and the lack of coordination of care for people with chronic conditions are a major cause for concern. The AHA believes that changes to the fundamental way in which care is delivered, including how the patient is incorporated into the care delivery and decision-making process and the way in which (s)he interacts with the care provider, is crucial to driving significant improvements in the quality and efficiency of care and patients' access to it. Given that over 86% of Medicare beneficiaries have one or more cardiovascular condition, attention to the delivery systems treating this population is particularly important.[1]

We believe that payment and delivery system reforms, such as the MSSP's accountable care organization model, hold promise for bringing about these

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[1] George Washington University analysis of 2008 Medical Expenditure Panel Survey data conducted for the American Heart Association.

changes. We have several concerns, however, with the way in which the MSSP is structured and the ability of CMS to ensure that the program is not abused to the detriment to patient care. In summary:

- The NPRM's method of beneficiary attribution coupled with potentially insufficient explanatory information for patients about ACOs, could cause confusion, distrust, and unnecessary switching of physicians which could ultimately be detrimental to patient care;
- The NPRM's vaguely explained monitoring mechanisms and oversight, particularly that aimed at identifying limitations on outside referrals and the avoidance of at-risk beneficiaries, inadequately protect patients from potential abuse;
- The proposed method for identifying the provision of primary care services for patient attribution disadvantages patients whose healthcare needs are dominated by a single complex chronic illness and who may currently receive a bulk of their care, both primary and specialty, from a specialist and could result in less continuity and coordination of care than they currently receive, with attendant deterioration in quality and increased cost;
- Proposed quality measure groupings and domain weighting create a performance scoring schema that could distort ACO success/failure rates, and potentially prohibit high-performing ACOs from receiving savings allocations, while still rewarding mediocre performance of other ACOs;
- Lack of specificity as to how ACOs should incorporate community organizations and existing successful quality improvement programs, as well as the lack of incentives to include them, could cause them to be overlooked as valuable partners in ACO efforts; and
- Potential impacts of the public reporting of ACO performance should be fleshed out more fully in order to avoid unintended consequences from reporting incomplete information too early.

Below, we provide further details on our concerns and the ways in which we propose CMS address them in the final rule.

Beneficiary Attribution and Information Transparency

The NPRM proposes the retrospective assignment of beneficiaries to an ACO based on the physician from which they receive a plurality of their primary care services. All ACO participating providers must prominently display their ACO participation and notify patients that they may opt-out of data sharing between CMS and the participating provider. CMS justifies choosing retrospective attribution, rather than prospective, since it will encourage ACO participants to employ quality improvement strategies on all patients, not just those who are ultimately attributed as beneficiaries of that ACO.

The AHA supports the full transparency of financial incentives under which a physician operates and the full awareness of these incentives by beneficiaries. We believe that prospective attribution is the best method to make patients fully aware of any incentives providers may have in delivering care and allow them to incorporate this understanding into the interactions they have with their care providers. While we commend the NPRM's attempts, via retrospective attribution, to encourage care coordination services, regardless of official ACO assignment, we are concerned that without prospective attribution, patients won't know definitively whether they are assigned to the ACO and whether provider incentives may be impacting their care. This situation has the potential to confuse beneficiaries, and in the absence of full information, create distrust in the system and even cause beneficiaries to unnecessarily switch physicians in order to opt-out of a program in which they may not even be included. The AHA strongly believes CMS should reconsider prospective attribution in order to maintain full transparency yet avoid this potential confusion.

If CMS determines that it is not possible to adjust the method of attribution, we believe our concerns could be mitigated, although not altogether eliminated, by a robust and comprehensive communications strategy. The creation of a communications strategy as proposed in Section II.D(5) will be key to educating beneficiaries about the ACO model. Consumers must understand not only that their provider is participating in an ACO and the data sharing that could occur between their providers and CMS, but also about the ways in which the ACO is structured, how physician performance will be measured and rewarded for both quality and cost improvements, and how any financial rewards will be allocated. They should also receive information that provides an in-depth explanation of their rights as patient participants in the ACO, including the appeals process and any potential recourse available to them.

In order to ensure the communications strategy is sufficiently strong and thorough, the AHA supports CMS' inclusion of all of the information proposed for inclusion in Section II.D(5). We also encourage CMS to go beyond just outlining the specifications for information that must be provided to patients and provide model language for notices and signage to be used by ACOs. CMS should also consider requiring ACOs to use this specific language. It is important that information is standardized, easily understandable and unbiased. CMS is in the best position to ensure the standardization of information across participating ACOs and should work with and seek input from organizations experienced with messaging complex healthcare information to consumers to determine its actual substance and format.

Patient Protections

The NPRM proposes mechanisms to protect patients from practices undertaken by ACOs that are intended to buffer them from negative performance scores, but that could also negatively impact patient care. The AHA commends the consideration of these very important issues, but is concerned that these proposed mechanisms may not be effective when implemented and the proposed recourse may not be strong enough when such practices are identified. These provisions are of particular concern to the AHA, given many CVD patients have rare conditions, such as congenital heart disease or hypertrophic cardiomyopathy, that require highly specialized, often high cost services that are not widely available. These patients, therefore, could be at risk of being targeted by physicians who may avoid these patients or limit the care they receive.

Prohibition on policies restricting referrals outside the ACO: In section II.B.9(d), the NPRM proposes prohibiting ACOs from "developing any policies that restrict a beneficiary's freedom to seek care from providers and suppliers outside of the ACO." We commend this prohibition to maintain a patient's access to care and also believe that it will help to differentiate the MSSP from the pitfalls and negative public perceptions associated with health maintenance organizations (HMOs) and their limitations on provider networks and services. That said, it is very difficult to identify instances when care should have been received but was not. CMS does not outline how it intends to do this, nor does it explain what the recourse will be when an ACO is found to have a prohibitive policy. Additionally, we believe that the prohibition should be broader, not just including explicit ACO *policies* against referrals outside of the ACOs, but also any tacit practices undertaken by ACO participants in response to the way in which the ACO allocates savings among participants. We would note that one major deficiency of HMO efforts was its inability to structure a model that effectively balanced appropriate, needed care referrals with cost control and patient protections. We would recommend that the subsequent versions of the MSSP regulation include in-depth explanation of the methodologies CMS will use to identify all limitations on care, as well as specific information on the recourse methods employed against violating ACOs.

Protecting patients' ability to seek care outside of the ACO, as well as encouraging physicians to refer patients for care outside of the ACO when in their best interest, is particularly important so as to not de-incentivize systems of care approaches at the regional/state level. In some cases certain hospitals or providers may not be the best or most appropriate ones to provide care to particular patients or for particular conditions. We are concerned that the ACO model could de-incentivize a system of care approach, by not allowing patients to seek care outside the network and only referring them to providers or facilities within the same network. For example, in some instances the type of rehabilitative services that are required for a patient may not fall within the care that is rendered by that specific ACO and its participating providers. If a provider feels that there is an incentive to refer that patient only to a provider within the network, this could end up inadvertently affecting readmission rates for those patients who could have benefited from rehabilitative services. We would strongly encourage CMS, therefore, to strengthen language in the rule to explicitly state that ACO efforts should not prevent system of care approaches that benefit patient care, even if that requires going outside the ACO.

Although we discuss the patient-centeredness criteria in more detail below, we would like to take this opportunity to voice our support for the specific criterion requiring ACO applicants to outline the process they will use to explain clinical knowledge and evidence-based medicine to beneficiaries. We believe that operationalizing this criterion will support patient protections by helping to foster discussion around treatment decisions and minimize the potential for abuse to occur, by making the patient more aware of physicians' treatment decision processes and empowering them to ask questions if they believe they are being limited in their care choices. We also encourage CMS to include patient education about appropriate care and clinical guidelines in the larger communications plan. Patients should be aware that clinical care guidelines exist and be able to ask their physicians how the care they are recommending does or does not align with established guidelines. Together, not only will these efforts help to protect patients and ensure they are receiving appropriate care, but also better educate the patient about their conditions and the ways in which is can be treated, making the overall system more patient-centered. We also recommend that CMS be very clear in defining "evidence-based," and support the use of trustworthy guidelines, as defined and recommended by the Institutes of Medicine in its recent report. We discuss this comment in further detail below.

Avoidance of "At-Risk" Beneficiaries: In Section II.H.1, the NPRM proposes a definition for "at risk" beneficiaries that would be used in the identification of instances when an ACO may be avoiding these patients. The NPRM defines such a beneficiary as someone having one or more of following factors: high CMS-HCC risk score, high cost due a set of listed factors, dually eligible for Medicare and Medicaid, high utilization, one or more chronic conditions, or new diagnosis expected to result in increased costs, and seeks input on the definition. The American Heart Association believes this definition is too vague to determine whether we support it. We request further information, including a list of the specific "chronic conditions" which would be included in this definition. Only at that point will we be able to determine whether the definition will enable the appropriate identification of instances in which patients are cared for differently or entirely avoided by a provider.

The NPRM goes on to propose a strategy to identify an ACO's avoidance of these particular beneficiaries that uses claims analysis and beneficiary-level documentation to identify trends and patterns suggestive of avoidance, including further investigation including follow-up with the beneficiary. An ACO found to be avoiding beneficiaries would be required to submit a corrective action plan (CAP) for CMS approval, outlining how the ACO intends to ensure that activities cease. The ACO would not receive shared savings for the period the ACO is under the CAP and could ultimately be terminated from the program if it fails to abide by the steps presented in the CAP.

Just as we pointed out above regarding the identification of ACOs with policies that limit referrals, we are concerned that these mechanisms will not be effective in actually identifying the avoidance of these patients. The minimal detail provided in the NPRM makes it unclear as to the exact process for determining "trends and patterns." Additionally, it is unclear how this definition would allow the identification of patients who will not have received care, as they are being avoided by the ACO. We appreciate the

> proposed follow-up directly with beneficiaries, but worry that what little is known about the process suggests that if avoidance is actually identified, it will only happen after a protracted process with significant delays caused by lags in the data reporting timeframe and time required for beneficiary follow-up. We encourage CMS to provide more detail as to the methodology it will use, as well as further information as to how this process may be more timely and responsive to actual delinquency.
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> That said, we do support the plan delineated by CMS by which ACOs will lose their certification if they act in ways to avoid high risk patients, although believe that more emphasis should be placed on the identification of the avoidance rather than punishment for the practice so the negative impacts of the practice may be caught earlier. We believe that routine audits are necessary to ensure that patients are not being avoided by the ACOs and recommend that CMS consider the Office of the Inspector General as the appropriate entity to externally review the activities of the ACOs and ensure they are not employing practices to filter patients and contribute to increased disparities in care.

Patient-Centeredness Criteria
Section 1899(b)(2)(H) of the Affordable Care Act requires an ACO to "demonstrate to the Secretary that it meets patient-centeredness criteria specified by the Secretary." The NPRM proposes that an ACO be considered patient-centered if it includes eight specific components and in most cases, requires the ACO to describe how it intends to meet those criteria in its initial application. The NPRM asks if any of the criteria are redundant – we do not believe so. Instead the criteria build on one another so to create a strong foundation to support overall quality improvement achieved by the ACO.

It is unclear, however, whether and how CMS intends to ensure that these principles are meaningfully implemented in the ACO and what recourse the ACO will suffer if they fail to meet the criteria. In only four of the eight criteria is there a proposed way to measure and validate the ACO's achievement of the criteria. In particular, we are concerned that there is no metric for either the diversity or individualized care plans for high-risk individuals criteria. We encourage CMS to attach metrics to all eight criteria to ensure that ACOs realize true patient-centeredness.

Oversight, Recourse, and Appeals Processes
As we have outlined in our comments above, the AHA has serious concerns regarding the oversight mechanisms and recourse methods proposed by CMS for behavior that limits patient access to care. We also have concerns that the proposed mechanisms to identify program delinquency are not adequate and encourage CMS to provide further explanation and details in the final rule on how it intends to oversee and enforce the correction of poor compliance.

For example, the proposed rule includes the development of an ACO compliance plan as part of its application materials that includes "a method for employees or contractors of the ACO, ACO participants, and ACO providers/suppliers to report suspected problems related to the ACO."

The NPRM, however, does not indicate to whom these complaints must be directed. We recommend in addition to an internal contact, such as the designated compliance officer for the ACO, that an external contact, such as CMS also be available to receive complaints. Since participants and providers/suppliers will be privy to the internal operations and management of the ACO, they must be empowered to report their concerns to someone external to the ACO. Patients should also be made aware of this oversight process and that it enables reporting to an external body. We recommend that CMS consider requiring ACOs to provide this information to patients in writing as part of the informational materials given to beneficiaries. Similarly, the NPRM proposes that CMS employ a range of methods to monitor and assess ACO performance, including analyzing beneficiary and provider complaints. Similar to the other assessment and evaluative methods proposed, we encourage CMS to offer further information as to how it intends to receive and monitor these complaints, as well as establish a threshold after which these complaints would trigger further investigation and action taken by CMS.

In this way, we believe that oversight must be strong enough so that program termination is not the only effective way to address poor ACO behavior. We request further development and explanation of these methods to ensure that they are adequate to meaningfully protect patients and encourage well-functioning ACO arrangements.

Primary Care Services

Section 1899(c) of the Act requires the Secretary to assign beneficiaries to an ACO ‘‘based on their utilization of primary care services’’ provided by a physician. However, the statute does not specify which kinds of services should be considered ‘‘primary care services’’ for this purpose, nor the amount of those services that would be an appropriate basis for making assignments. In this proposed rule, CMS delineates three options. They are:

1. Assignment of beneficiaries based upon a predefined set of “primary care services”;
2. Assignment of beneficiaries based upon both a predefined set of “primary care services” and a predefined group of “primary care providers”; and
3. Assignment of beneficiaries in a stepwise fashion.

CMS proposes to adopt Option (2) but asks for comments on this decision. In addition to the potential geographic disadvantages CMS acknowledges, the AHA is concerned that assignment Options (2) and (3) might result in disadvantage for those patients whose healthcare needs are dominated by a single complex chronic illness. Such patients may currently be receiving the bulk of their care, both primary and specialty, from a specialist. Assignment of such patients to an ACO whose physicians are only generalists is likely to result in less continuity and coordination of care than they currently receive, with attendant deterioration in quality and increase in cost.

We strongly urge CMS to consider adopting an approach that would allow those specialists who are willing to take on the role of primary care physician to be designated as the primary provider of the beneficiary. CMS should allow specialists to agree to the same terms as primary care physicians, with the specialist entering into a contract for the provision of primary care services. We believe that allowing this flexibility will foster the development of creative ACO structures, perhaps spurring some specialists to become more oriented to comprehensive care and some generalists to develop specific skills in certain chronic diseases. We believe that this is not only in the best interest of the many patients receiving comprehensive care from a specialist, but also supports innovation in care delivery, a goal supported by the ACA.

Data Sharing

In the proposed rule, CMS plans to provide aggregate data reports to ACOs which would include, when available, aggregated metrics on the assigned beneficiary population and the beneficiary utilization data at the start of the agreement period based on historical data used to calculate the benchmark. CMS is further proposing to include the data in conjunction with the yearly financial and quality performance reports, and would also provide quarterly aggregate data reports to ACOs based on the most recent 12 months of data for potentially assigned beneficiaries. CMS is requesting feedback on this proposal as well as the kinds of aggregate data and frequency of data reports that would be most beneficial.

The AHA supports CMS' efforts to provide the ACOs with aggregate data. At the onset ACOs may not have the necessary data available to assess whether and what gaps in care exist. Aggregate data can provide the ACOs with a reference point to determine best strategies to improve patient care. For example, having access to quality performance data would provide them with a baseline for their region which they could use to help improve the quality of care rendered to beneficiaries. Performance data may help ACOs assess where additional efforts need to be made in order to improve care for patients (e.g. need to reduce readmissions, need to increase number of preventive screenings).

Additionally, CMS is proposing to provide ACOs with beneficiary identifiable data. Specifically, CMS is proposing to disclose the name, date of birth, gender, and Health Insurance Claim number of the historically assigned beneficiary population. The Agency notes that this information is helpful in allowing ACO providers to identify the beneficiaries and allow them to review their records and target care processes in need of change. By knowing individuals assigned in the past, CMS hopes that this would help ACOs identify individuals who may benefit from improved care coordination strategies going forward.

We understand the value in sharing personal health information with ACOs and acknowledge that CMS plans to prevent actions by ACOs to avoid patients, especially those who are chronically ill, such as patients with CVD and stroke. We also recognize, however, that providing this information to providers could also enable them to identify undesirable patients and enable their avoidance of providing care to them. Therefore, in reinforcement of the comments made above, we support the plan delineated by CMS by which ACOs will lose their certification if they act in ways to avoid high risk patients. We believe that this type of analysis should be undertaken by the Agency on an ongoing basis. Those ACOs that are identified as avoiding patients should have their contract terminated, and a list of those ACOs who have lost their status should be made publicly available. Furthermore, we believe that routine audits are necessary to ensure that patients are not being avoided by the ACOs. Additionally, the Office of the Inspector General may be an appropriate entity to externally review the activities of the ACOs to ensure that these activities do not contribute to increased disparities in care.

Quality Measures

The AHA would like to make the following comments regarding the proposed 65 measures included in the draft ACO rule.

Patient Experience Measures: The AHA supports the inclusion of the patient experience measures in the ACO measure set. We believe that these measures are important in assessing how the patient evaluates the care that was provided.

Outcome Measures: Seven of the eight "outcomes" measures in the care coordination domain (No. 12-18) are AHRQ PQIs (Prevention Quality Indicators) that measure admissions per 100,000 population for various conditions (e.g., CHF, pneumonia, diabetes, dehydration, COPD). According to AHRQ, these PQIs "identify hospital admissions in geographic areas that evidence suggests may have been avoided through access to high-quality outpatient care."[2] The original intent of the AHRQ PQI measures was that they were developed to identify regional/geographic issues that would assist health planning authorities. These measures do not seem to have been designed to assess the quality of specific providers, and it is unclear how these will be used to assess an ACO's ability to improve quality of care. In the proposed rule, CMS states that the PQIs for geographic regions would not seem plausible as an ACO quality metric. Therefore, we would ask for clarification if CMS plans to re-define the population denominator as those patients covered by an ACO. Even if this is the case, there are factors outside the control of the ACO that will impact these population rates. This concern was acknowledged by AHRQ when they originally developed the PQI measures for regional assessment:

> "Although other factors outside the direct control of the health care system, such as poor environmental conditions or lack of patient adherence to treatment recommendations, can result in hospitalization, the PQIs provide a good starting point for assessing quality of health services in the community."[3]

Such concerns are even more relevant when these metrics are used to assess and compare the quality of ACOs that may care for populations with vastly different socioeconomic and demographic characteristics. For some populations, the rate of many of these PQIs may be refractory to the best efforts of well-intentioned ACOs and physicians, irrespective of their commitment to mitigate disparities in care. In fact, if these measures are used to assess ACOs, those ACOs which care for disadvantaged populations may be rendering better care if they preferentially admit some patients with dehydration, pneumonia, or COPD

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[2] http://www.qualityindicators.ahrq.gov

[3] http://www.qualityindicators.ahrq.gov/Modules/pqi_overview.aspx

exacerbations, as their outpatient environment and resources may be quite problematic compared with those of more affluent populations.

General Comments: We would take this opportunity to stress the important role that ACOs play in helping providers identify tools that can help improve the quality of care for their patients. The AHA believes that for ACOs to be successful they must help further the sharing of best practices and the use of clinical decision support tools, as well as encourage providers to engage in quality improvement efforts. Registries are one means by which providers can help improve the quality of care rendered to patients by providing users with reports on measures on a more frequent basis (at least quarterly) versus the annual feedback reports. This allows providers to identify areas where care needs to be improved and allows them to meet with their colleagues and identify strategies by which to improve care on a more frequent basis. The AHA has a suite of registries for the inpatient and outpatient setting such as Get With The Guideline-Heart Failure, Get With The Guideline-Stroke, Get With The Guidelines-Resuscitation, ACTION Registry-GWTG and The Guideline Advantage©.[4] Each of these modules collects a number of measures and provides hospitals and physician groups with quarterly reports that allow them to assess their performance compared to national benchmark data. Registries such as these should be utilized in order to achieve the goals of the ACOs which include reducing readmissions and furthering care coordination.

Evidence Based Guidelines and Health IT Infrastructure

In this way, the AHA applauds CMS' requirement that ACOs implement evidence based practices and guidelines and have an information technology infrastructure capable of collecting and evaluating data so that it may be used to provide feedback to ACO providers, including at the point of care. As we explained above, the AHA's quality improvement suite of programs is based on the idea that providers have access to clinical care guidelines and patient information at the point of care and receive regular feedback comparing their performance to national benchmarks to improve the quality of the care they deliver.

We believe, however, that the ACO application requirement should be strengthened so that ACOs are required to document specifically how it plans to meet this requirement for high prevalence conditions such as cardiovascular disease that have significant mortality and morbidity impacts on patients, as well as bring about considerable costs to the overall health care system. With over 86% of the Medicare population having one or more cardiovascular condition[5], requiring ACOs to explain how they intend to target this, and other conditions, could bring about large improvement in the quality of care delivered and the health of these patient populations, while also reducing costs. This increased specificity would also be consistent with, and supportive of, the National Health Care Quality Strategy, the fourth aim of

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[4] From an inpatient setting, the AHA/ASA programs include GWTG-Heart Failure, GWTG-Stroke, GWTG-Resuscitation, and ACTION Registry-GWTG. In addition to the data collection capabilities referenced above, these registries also contain other quality improvement resources, including access to rationale/logic, guidelines/statements, real time logic checks, coding instructions, and webinars.

[5] George Washington University analysis of 2008 Medical Expenditure Panel Survey data conducted for the American Heart Association.

which is to promote "the most effective prevention and treatment of the leading causes of mortality, starting with cardiovascular disease."[6]

We also recommend that the ACOs should be required to implement "trustworthy" guidelines as defined by the recently released Institute of Medicine report. There must be a bar which the guidelines used and promoted by ACOs are measured and we believe the IOM's eight standards provide the appropriate criteria. Additionally, CMS should encourage ACOs to ensure that providers have access to the most up to date evidence based guidelines, as well as access to the tools and programs that incorporate these guidelines and their updates and facilitate the use of the guidelines in care delivery. The AHA's GWTG programs are examples of existing tools that ACOs could leverage to incorporate these guidelines into practice. In the case of GWTGs, the inpatient programs are updated annually to reflect changes in evidence based guidelines, including updated rationale/logic statements, updated measure specifications, and coding instructions to ensure that the patients are receiving the recommended care.
Similarly, in The Guideline Advantage©, a tri-agency program with the American Cancer Society and the American Diabetes Association, we ensure that the program has incorporated the latest measures, developed by the AHA with is co-developers, and we continue to access independently created measures developed by external organizations (e.g., NCQA) for inclusion in our program. We also regularly review the measures that are currently endorsed by NQF for potential inclusion in The Guideline Advantage©. We believe that programs such as ours, that use the HIT infrastructure to support the availability of evidence based guidelines, should be used by ACOs to support quality improvement in the assigned beneficiary population.

Governance and Partnerships
As we have noted a few times, the AHA encourages CMS to support ACOs' use of existing quality improvement programs and tools. In this same vein, we also recommend that CMS provide further detail related to its statement that "the ACO must establish partnerships with community stakeholders to advance the three-part aim." We believe that by not specifying the types of organizations with which partnerships would best achieve the triple aim, such as public health agencies and volunteer health organizations, including the American Heart Association, CMS misses an opportunity to network ACOs with successful local and regional quality improvement efforts. These existing entities have worked hard over long periods of times to establish relationships and develop patient and stakeholder networks which the ACO could tap into and leverage in order to best address the needs of the community. These organizations are also aware of the barriers that exist and what resources and strategies the ACOs could deploy in order to address them and achieve meaningful improvement. We also encourage CMS to be very specific about the expectation for these relationships to ensure that the ACOs capitalize on all potential synergies to bring about quality improvement.

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[6] National Strategy for Quality Improvement in Health Care, March 2011. Accessed March 21, 2011 at www.healthcare.gov/center/reports/quality03212011a.html

Rural Exemptions and Adjustments

The NPRM proposes adjustments for ACOs meeting certain criteria, such as rural location, high participation by solo practices, or a strong presence of federally qualified health centers (FQHCs) or rural health centers (RHCs). The AHA is very aware of the unique and additional challenges faced by rural providers as compared to those in more urban areas and supports CMS' attempt to adjust the model to account for them. We believe, however, that additional efforts will be necessary for ACOs to be viable in rural areas.

Telemedicine, for example, may be the only mechanism that rural providers have to coordinate care among physicians and patients who are located across great distances. Barriers created by the lack of reimbursement for many telehealth services, aside, implementing telehealth requires financial investments in technologies, as well as resource adjustments and workflow changes that take time to fully incorporate into practice. We have concerns, therefore, that the adjustments proposed in the rule may not be sufficient to surmount these financial obstacles. In this way, CMS should assess the experience of rural ACOs in dealing with these differences and potentially increase the size of the incentive in future years to account for these additional efforts.

It is also possible that rural providers may actively work to improve quality yet not achieve demonstrable improvements and associated cost reductions until several years into the program. The population that is treated by rural providers is very different from urban providers. For this reason, we encourage CMS to evaluate the size of its adjustments after a few years of the program to make sure they are appropriate to the realities of these geographic locations and unique populations. We also recommend that CMS provide special evaluations of rural ACO programs. These ACOs may have developed models to address their unique circumstances, which should be shared across rural providers. These best practices, however, may not have met the MSSP targets within the specified timeframe. In this way, CMS should consider additional adjustments and exemptions of these providers, including delayed evaluation of their cost saving potential or an increased adjustment threshold.

Scoring and Domain Weighting

In the proposed rule, CMS delineates five domains of care in which the proposed measures are categorized:

- Domain 1: Patient/Caregiver Experience - 7 measures
- Domain 2: Care Coordination - 16 measures
- Domain 3: Patient Safety - 2 measures
- Domain 4: Preventive Health - 9 measures
- Domain 5: At Risk Population/Frail Elderly Health - 31 measures

CMS goes on to describe the methodology for calculating scores within and across domains, giving each domain equal weight. Although the use of domains is a useful tool to visualize the distribution of metrics, the AHA has concerns with the implementation of such a model. As can be seen above, these domains vary greatly in the number and type of measures they contain, as well as the scoring methodology, the reliability of their component measures, and the degree to which measures are tightly linked to outcomes. We would note that even though the domains vary substantially in the number of measures they contain, each domain would receive equal weighting under the proposed rule. The AHA is concerned with this approach, as it could create distortions when applied and make it seem like inadequate care is being provided to the patient, when this is not the case. For example, equal weighting creates a situation in which a poor domain score due to low performance on just one measure is 15 times as great for the patient safety domain as the at-risk population domain.

With respect to the "all or none" measures, we agree with their intent to encourage providers to strive to provide appropriate care. The AHA would like to take this opportunity to refer CMS to our position paper on composite measures for a number of potential issues that should be considered before implementing such measures.[7] Scoring on all or none measures, however, has several problematic elements. For example, the following situations occur:

- Disproportionate impact of just one poorly specified measure that does not account for all appropriate exclusions;
- Impact of missing data for one measure; and
- One out of five failure receives the same score as four out of five failure.

While it does demonstrate the percentage of patients to whom a provider gives all recommended care, it would not show any difference in score between a reporting period when an ACO was providing, on average, three of ten recommended measures versus a subsequent period when they were providing nine of ten recommended practices, which is clearly a substantial degree of improvement. We recognize that CMS is proposing to have each individual metric of the composite measure also as a separate measure, but we feel that this still does not address our concerns. Individual failures are essentially "double counted"— they impact the score for the individual metric and they result in a zero score for the associated all-or-none composite. CMS states that "ACOs that do not meet the quality performance thresholds for all proposed measures would not be eligible for shared savings, regardless of how much per capita costs were reduced. Given our concerns regarding the increased potential for failure on some domains and measures, this approach has substantial ramifications. Therefore, we would strongly urge CMS to not adopt all or nothing measure for ACOs. We would, however, support the inclusion of the composites' individual metrics as individual measures in the ACO quality measure set.

As a final observation, the use of scoring via domains (if publicly reported) could provide an inaccurate picture of the type of care that is being rendered to patients serviced by the ACO. Given that ACOs are intended to facilitate the provision of high quality healthcare for patients, we remain concerned that such a weighting/domain mechanism may inadvertently create

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[7] ACCF/AHA 2010 Position Statement on Composite Measures for Healthcare Performance Assessment: American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures (Writing Committee to Develop a Position Statement on Composite Measures). Eric D. Peterson, Elizabeth R. DeLong, Frederick A. Masoudi, Sean M. O'Brien, Pamela N. Peterson, John S. Rumsfeld, David M. Shahian, and Richard E. Shaw. Circulation. 2010;121:1780-1791.

disparities in care. To avoid such unintended consequences we would ask that CMS not adopt the proposed model.

Public reporting

In the proposed rule, CMS states that it plans to publicly report information on ACOs including basic information such as name/location and primary contact, as well as organizational information including ACO participants, identification of ACO participants in joint ventures between ACO professionals and hospitals, identification of ACO participant representatives on its governing body, and associated committees and committee leadership. Additionally, the proposed rule states that certain shared savings information, such as amount of shared savings/losses and total proportion of shared savings invested in infrastructure, should also be reported. Furthermore, CMS states that ACOs must make information on its accountability for the quality, cost, and the overall care furnished to its assigned beneficiary population, available to the public.

When determining the specifics of the public reporting components of the ACO program, we encourage CMS to work with different stakeholders to determine how and what type of information collected from ACOs should be posted and the format in which this information should be made publicly available. We have concerns about the potential unintended consequences of posting incomplete information too quickly. Despite the preventative measures proposed by CMS, this new program may still be gamed, so it will be important to be able to review and evaluate the first year's data before identifying what information should be publicly reported. We believe that this is appropriate given it is consistent with previous initiatives, such as Hospital Compare, in which very little data was released the first year to ensure that the data could be validated and to avoid, to the extent possible, unintended consequences. For example, because ACOs will receive data from CMS (aggregate and patient-level), ACOs may target their efforts on specific measures or conditions. If a region has high readmission rates, the ACO may focus its efforts on follow-up care to reduce this number. The AHA encourages participating providers to use data to inform its quality improvement efforts, but would also note that such targeted efforts may initially increase costs due to more follow-up care being provided. If costs do initially increase to reduce hospital readmissions, the public reporting of this information without linking it back to reduced readmissions may give the appearance that the ACO is not providing adequate care.

Similarly, data reported on ACOs should not purely reflect cost but should also be linked to the improved quality of care that was rendered to beneficiaries in the ACO's region. It is important to ensure that any cost data is always linked back to quality of care data in an easily understandable way. Failure to do so may cause users of this information to think that the ACO's cost reductions also reflect improvements in care.

Additionally, we believe that it is important to adjust public reporting schemas based on the types of populations. As we noted above, in our concerns related to adjustments for rural ACOs, these providers may have to overcome different barriers than metropolitan areas to improve performance. We also have concerns about potential consequences depending on the population treated by a specific ACO. Those ACOs that treat sicker or poorer populations should not be penalized via publicly reported data. Even within urban regions there are different demographics; comparing those ACO scores online for those treating sicker patients as compared to those ACOs treating healthier patients, may provide an inaccurate picture of the care and outcomes of each ACO's applicable population. There must be some means by which to acknowledge these differences due to varied environments when posting this information publically.

Furthermore, it is important that CMS ensure that public reporting of information by ACOs does not inadvertently increase disparities. While CMS states its plans to institute measures to prevent the avoidance of certain patients, publicly reporting information and the attention it draws the ACOs to which it refers, may inadvertently foster an environment in which co-morbid patients are avoided. Therefore, it is important for CMS to address how different states and regions may have different population mixes that could affect the improvement in quality of care.

Conclusion
We appreciate the opportunity to share the perspectives of cardiovascular disease and stroke patients with you and offer the AHA staff as a resource as you consider adjustments in the final rule. If you have questions or need additional information, please do not hesitate to contact Madeleine Konig in our Washington, DC Advocacy office at 202.785.7930 or Madeleine.Konig@heart.org or Penelope Solis in our Quality Improvement office at 202.423.3124 or Penelope.Solis@heart.org.

Sincerely,

Ralph Sacco, MD, FAHA
President
American Heart Association