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Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Proposed Rule CMS-1345-P; 76 *Fed. Reg.* 19,528

Dear Administrator Berwick:

The American Medical Association (AMA) appreciates the opportunity to provide our views concerning the Centers for Medicare and Medicaid Services (CMS) proposed rule on *Medicare Shared Savings Program: Accountable Care Organizations* (ACO Program). The AMA also appreciates CMS' work in developing a proposal to implement Section 3022 of the Patient Protection and Affordable Care Act (ACA) to begin to test new delivery and payment models allowing physicians and other providers to improve care for seniors in ways that generate savings for the Medicare program, and to share in a portion of those savings. Developing and testing ACOs can be an important step in transitioning to an array of new approaches to Medicare physician payments appropriate for a post-sustainable growth rate (SGR) era.

The AMA is pleased to provide our views and recommendations for revising the proposed rule so that the ACO model can be tested in a broad spectrum of physician practices. We are confident that a well-developed ACO model can be an effective tool to improve quality, manage care coordination, reduce health care costs, and create a supportive environment for practicing physicians. **Since this is a completely new Medicare delivery and payment model, the AMA urges CMS to issue an interim final rule, rather than a final rule, so that CMS maintains the flexibility to modify and improve the ACO regulations as the agency learns more about this model.**

PAYMENT AND RISK STRUCTURE

The AMA urges CMS to provide a payment option that includes shared savings only (“one-sided risk”) without the mandatory shared loss provision. We believe an option allowing ACOs to receive shared savings, without the down-side risk, will encourage participation by a

greater variety of physician practices. The AMA also urges CMS to allow providers to bill Medicare for currently unbillable procedures under payment models that include down-side risk.

Implementing a Pure Shared Savings Model

Section 3022 of the ACA added Section 1899(d) of the Social Security Act, which authorizes paying ACOs a share of the savings they achieve for Medicare, without being at risk for losses. In the proposed regulations, however, CMS chose not to implement this program at all, but only to implement two “other payment models” using the authority under Section 1899(i). Each of these proposed payment models requires that ACOs pay a penalty to Medicare if costs for their patients increase beyond the levels projected by CMS. Under the first of these models (“Track 1”), ACOs will be eligible for shared savings during their first two years, similar to what Section 1899(d) authorizes, with no down-side risk. During year three, however, the ACO would have to repay a share of any losses Medicare experiences compared to the benchmark. In Track 2, ACOs will face down-side risk in each year of the program.

There are several important reasons why it is inappropriate to force all ACOs, particularly small ACOs and physician-driven ACOs, to accept down-side risk, particularly during the initial implementation of ACOs. In particular:

- **Lack of data.** Prospective ACOs still have no access to Medicare claims data that would enable them to evaluate the nature or magnitude of the down-side risks they would be accepting. The smaller the ACO, the more likely that its patients are currently receiving some of their care from physicians or hospitals that are not part of the ACO.
- **Retrospective assignment of patients and lack of a supportive benefit design.** Under the proposed regulations, ACOs would not even know which beneficiaries would be assigned to them until after the fact, and those beneficiaries would have no obligation or incentive to cooperate with an ACO’s efforts to control expenditures.
- **Lack of risk-adjustment.** Under the proposed regulations, there would be no adjustment of the benchmark based on changes in the health status of the patients attributed to the ACO. An ACO which attracted a larger proportion of sicker patients due to its better care coordination services could experience increased costs simply because its patient population changed over time, and requiring it to pay Medicare for a share of those costs would essentially be forcing the ACO to provide reinsurance to CMS, rather than the other way around.
- **Costs driven by non-physician providers.** A physician-only ACO could experience increased costs for its attributed patient population due to actions taken by the local hospital(s) or other non-physician providers that were out of the control of the ACO. Even if the higher costs were lower than they would have been in the absence of the ACO’s efforts, under the proposed regulations, the ACO would be penalized for the

increases in the portion of the costs that it could not control, rather than being rewarded for decreases in the portion of costs that it could (and did) control.

CMS states that the two-sided risk approach is designed primarily to provide stronger incentives to ACOs to control spending and achieve efficiencies. The AMA cautions that the ACO program is a completely new program, and it is intended as one model, among many, that could form the basis of a new delivery and payment system under Medicare. If proposed ACO models are too restrictive, participation by physician groups could be unnecessarily limited. This would be a missed opportunity to fully explore this new care delivery and payment model for the Medicare program. Therefore, strong incentives are necessary to spur participation in the program.

Further, there is already a risk of substantial loss for new ACOs because the up-front investments needed to build the appropriate ACO infrastructure are extraordinarily steep. Based on the Physician Group Practice (PGP) Demonstrations, CMS has estimated that ACOs, on average, will require an up-front investment of \$1.7 million, and the American Hospital Association estimates that cost at more than \$11 million. With 78 percent of office-based physicians in practices of nine physicians and under, and the majority in practices of four physicians or less, it is difficult for physician practices to access this kind of capital. There is also no guarantee that an ACO will achieve necessary savings, much less recoup their up-front investment. Therefore, it is critical that CMS seek to minimize the down-side risk of this new program and allow at least one option for shared savings only. If potential ACOs wish to receive a greater share of the up-side risk by participating in shared losses as well, CMS can also offer this option.

In addition, the AMA believes that physician groups and other providers that choose to participate in the ACO program, which requires investment of significant resources, would have a built-in incentive to control costs and achieve efficiencies. This is how the ACO will recoup their investment and avoid large losses. Also, their desire to completely transform their practices to meet the requirements to become an ACO, by definition, means they have a strong interest in providing efficient and high quality of care to their patients to help lead the way into a new mode of payment and delivery of care.

Physician-driven ACOs have a unique and important role to play as we move forward with testing the ACO model. In particular, physician-practice led ACOs will have a strong incentive to improve the quality and efficiency of care, while reducing costs through initiatives such as reducing hospital admissions and readmissions. This is in contrast to hospital systems that do not have this same incentive to reduce initial admissions because this would reduce the hospital's revenue stream. Therefore, CMS should ensure that smaller, physician-driven ACOs have significant incentives and opportunity to participate in the ACO program. A shared savings model, without down-side risk, would be an important step in that direction.

Because of the foregoing concerns, the AMA urges CMS to allow at least one option by which an ACO may share in the savings, as contemplated by the statute, without the down-side risk.

Alternatively, at a minimum, CMS could provide a shared savings option, without downside risk, to those ACOs that qualify for the proposed exemption to the two percent net savings threshold, as discussed in the proposed rule at 76 Fed. Reg. p. 19,613. Under this proposal, Medicare would not retain the first two percent of savings achieved by smaller ACOs with less than 10,000 assigned beneficiaries and that meet one of four requirements set forth in the proposed rule, including that the ACO is composed only of professionals in group practice arrangements or networks of individual practices of ACO professionals. Instead, these ACOs would share on first dollar savings. CMS' rationale for this small ACO exemption is that smaller physician-driven ACOs have the potential to improve the quality and efficiency of care, but challenges, such as accessing capital, may prevent them from assuming risk right away. The AMA agrees with CMS that these smaller physician-driven ACOs have unique challenges that other large provider networks do not experience. Therefore, in the final (or interim) rule CMS should tailor provisions to reach out to these physician practices. **We agree with the proposal to allow these smaller ACOs to share in first dollar savings, and we urge CMS to retain this proposal. In addition, we urge CMS to broaden this smaller ACO exemption by allowing these ACOs the option of sharing in savings only, and not assuming the risk on losses.**

Adding Flexibility to Fee-for-Service Payment

In the proposed regulations, CMS chose to use its authority under Section 1899(i) to create two payment models that include down-side risk, but it did not use that same authority to create a payment model that would actually change the underlying fee-for-service structure in ways that would support better and more efficient care for patients. For example, under Medicare's current payment system, a physician can be paid for seeing a patient in the office, but not for talking to the patient on the telephone. This means that if a telephone consultation would more promptly and conveniently enable a patient's concern to be adequately addressed than an office visit, a physician who speaks to the patient on the telephone rather than asking them to come to the office will lose money.

There are CPT codes for telephone calls and other non-face-to-face services, and there are relative values units assigned to them, but these codes are not authorized for payment by Medicare. **The AMA recommends that CMS use its authority under Section 1899(i) to authorize payment for these codes for ACOs that accept down-side risk if the ACO uses them as part of their efforts to better manage care for their patients. CMS should then collect data on the impact of paying for these services to determine if such payment policy should be expanded to fee-for-service Medicare.**

The AMA believes that authorizing payment for these codes will actually reduce overall expenditures for Medicare (by reducing preventable hospital admissions and acute care episodes), as well as improve quality and patient satisfaction. If CMS applies this policy to Track 2, if an ACO bills for these codes, but fails to achieve offsetting savings in other areas and thereby increases total Medicare expenditures, the ACO would be required to repay CMS for more than half of the increased costs.

At a minimum, CMS should authorize payment for these codes as part of Track 2 for small physician-only ACOs, since they will be the least likely to have access to capital reserves that could cover short-term losses incurred by shifting care from currently billable to currently unbillable procedure codes.

Allowing First-Dollar Sharing of Savings for All ACOs

In implementing shared savings payment models, the AMA urges CMS to allow ACOs to share in a percentage of all savings that are achieved, rather than simply sharing in the savings above the minimum savings threshold proposed in the rule. CMS proposes this minimum threshold due to a concern that an ACO's savings may be due to random variation in spending rates and not due to their own performance. The AMA believes that due to the significant upfront capital investment and other resources needed to operationalize an ACO, it is unlikely that savings would be random. The potential that they would have to meet minimum savings rates of up to almost four percent before sharing in any savings will put participation in an ACO outside the reach of smaller networks and potentially diminish provider competition, thereby creating monopoly networks that then can raise prices to private payers and eventually to Medicare as well. Moreover, even if the savings in the initial years of an ACO's contract were random, Medicare could still profit in the out-years if the ACO was able to finance the necessary practice re-tooling, provide better care, gain the necessary experience to improve upon its performance in a subsequent contract, and ensure continued competition among providers in its community.

Higher Shares of Savings for ACOs

Under the proposed rule, CMS has made it extremely difficult for successful ACOs, particularly small ACOs, to obtain funding to cover the costs they incur in improving care. First, the ACO must achieve a minimum percentage savings in order to prove that the savings are not "random," and the percentages are very high for small ACOs. Second, except for the smallest ACOs, CMS keeps the first two percent of any savings that are generated before the ACO is eligible for any share of the savings. Third, CMS only shares at most 50 percent to 60 percent of the savings beyond that two percent. Fourth, the savings percentage is reduced based on an ACO's performance against quality standards that have not yet been defined. Fifth, the savings that an ACO can receive is capped at 7.5 percent to 10 percent of the baseline expenditure. Sixth, 25 percent of the savings share that ACOs do qualify for is retained by CMS as a hedge against the need for the ACO to pay CMS for cost increases in future years. Seventh, the savings share is not paid for a year after the end of the year in which the savings are actually achieved.

Recognizing that most ACOs will need to make significant upfront investments in improved care management and may lose significant amounts of fee-for-service revenue, such as by preventing hospitalizations and shifting care to currently unreimbursed services, these restrictive rules, combined with the uncertainty about whether savings can be achieved, will deter many providers, particularly small physician practices, from participating. **CMS should increase the percentage of savings that ACOs can receive, particularly in the initial years.**

Withholds and Lines of Credit

To ensure that ACOs can repay Medicare their share of any losses that exceed their benchmark, CMS is proposing a flat 25 percent withholding rate applied annually to an ACOs earned performance payment, along with other repayment options, such as Medicare access to an ACO's line of credit.

This provision is fundamentally illogical, since it penalizes the best-performing ACOs, yet has no impact on the poorest-performing ACOs. If an ACO achieves no savings during the first two years, it would be the most likely to experience cost increases during the third year, but nothing is withheld from that ACO during the first two years because there is nothing to withhold. In contrast, if an ACO achieves savings during the first two years, it would be the least likely to experience cost increases in the third year, yet CMS would withhold 25 percent of the share of savings it does achieve during the first two years in the unlikely event that a cost increase would occur by the third year. The better the ACO performs in the first two years, the bigger the penalty this provision imposes, since it is based on a percentage of the savings the ACO achieves, not on the total expenditures it is working to reduce.

CMS is already retaining the first two percent of any savings and 50 percent of any savings beyond that for most ACOs, so even in the unlikely event that an ACO should experience cost increases in the third year, after having achieved savings in the first and/or second years, and is unable to pay CMS its share of that cost increase, CMS would still achieve net savings over the life of the agreement.

Consequently, all this provision does is penalize the best-performing ACOs and make it even more difficult for them, particularly the small physician practice-driven ACOs, to make the upfront investments needed to achieve savings for Medicare, and therefore we urge that this provision be dropped.

Lack of Risk Adjustment During the Performance Period

The proposed regulations do not appear to provide for any adjustment in the expenditure benchmark during the performance years of the agreement based on the health status of the ACO's patients. This could represent a serious problem, particularly for smaller ACOs. If the ACO's patients become sicker over time during the performance period, they will inherently incur greater costs, even if the ACO is keeping those costs lower than they would have been had the patients been cared for outside of the ACO. Moreover, if an ACO demonstrates that it has the ability to provide improved care coordination services for individuals who have multiple health conditions, it could well attract a disproportionate share of such Medicare beneficiaries. Even if the ACO successfully reduces costs for these individuals beyond what they would have been had the beneficiaries seen other providers, the fact that the individuals will still need more services than other beneficiaries with lower acuity will make the ACO's total expenditures increase beyond what they would have otherwise been. This would reduce the likelihood that CMS would calculate savings under the methodology in the regulations and award the ACO a

share of those savings, and increase the likelihood that CMS would calculate an increase in costs and require the ACO to pay a share of those costs.

CMS should be trying to encourage ACOs to attract high-cost beneficiaries and find ways to improve the quality and reduce the costs of their care, but this cannot be done without some kind of appropriate risk/severity adjustment in the benchmark calculations for the performance years, and not just adjustments purely for age and sex.

Outliers

The AMA is concerned about outlier patients assigned to an ACO that have exorbitant medical costs. It is quite likely that ACOs would have at least several beneficiaries with unusual circumstances whose care may cost well into the hundreds of thousands or millions, putting the ACO's aggregate costs far out of proportion to its benchmark. This could occur despite an ACO's best efforts to improve care and reduce costs. In fact, CMS has provided protection for this possibility to ACOs that participate in the Pioneer ACO model through the Center for Medicare and Medicaid Innovation. CMS states that it "aims to encourage Pioneer ACO participation by avoiding arrangements that put Pioneer ACOs at excessive financial risk. At the beginning of each performance period, Pioneer ACOs may opt to have CMS subtract from the expenditure baseline, the expenditure benchmark, and the actual Medicare expenditures for their aligned beneficiaries, any claims above the 99th percentile for national per-capita expenditures. In this case, the matched cohort used for benchmark expenditure calculations for the ACO will be adjusted accordingly. Alternatively, the ACO may purchase equivalent coverage from the private sector." **The AMA urges similar protection for ACOs under the ACO Shared Savings Model through an exemption allowing ACOs to exclude the costs of caring for outlier patients when calculating the savings achieved in comparison to the benchmark.**

NEED FOR ADDITIONAL PAYMENT MODELS

The AMA urges CMS to include several transitional ACO models, such as partial capitation and other payment models, in the ACO final (or interim) rule to encourage participation by small and solo physician practices. In implementing these types of payment models, we also urge CMS to allow these alternative ACOs to share in a percentage of all savings that are achieved, rather than simply sharing in the savings above the minimum savings threshold proposed in the rule.

The law permits CMS to establish partial capitation and other payment models that the Secretary of the Department of Health and Human Services (HHS) determines will improve the quality and efficiency of Medicare services. The AMA is disappointed that CMS did not exercise its discretion to include any of these alternative models in the proposed rule. We are encouraged, however, that CMS plans to address these models through the Center for Medicare and Medicaid Innovation, and we look forward to working with CMS in their development. **We also strongly urge CMS to add these models as options in the ACO final (or interim) final rule.**

The AMA believes the ACO program will be undermined without alternative payment models. The ACO program is a new program intended to break new ground, and some experimentation will be needed to achieve this goal. If the ACO program is a one-size-fits-all design that is available only to large groups that already have the needed infrastructure and care management programs in place, no new ground will be broken. Further, if the program is only accessible to providers with access to large amounts of capital, it will likely result in the creation of new or larger monopolies that ultimately will increase health care costs. The AMA has provided a number of recommendations to CMS for transitional models that could potentially be more accessible to small practice, physician-driven ACOs. It is imperative to reach out to these types of practices because they have limited or no access to the capital and other resources needed for a successful ACO.

Further, these practices have limited experience with some of the tools needed to implement new payment and delivery models, such as: (1) the ability to obtain and analyze large amounts of data on patient utilization and costs for their own services as well as services provided by others; (2) skills to redesign processes to take advantage of new payment models and to report performance measures; (3) ability to identify inappropriate utilization and reduce it; (4) ability to share information with other physicians and providers at the point of care; and (5) ability to manage patient care in a coordinated way and experience managing risk. With the vast majority of medical practices qualifying as small businesses and involving a small number of physicians, it is important to put in place transitional models that will help small and solo practices to develop these capabilities.

To address these limitations, the AMA recommends that several transitional models be tested under the Medicare ACO program, as described below. A more detailed discussion of these and other transitional approaches is available in “Transitioning to Accountable Care: Incremental Payment Reforms to Support Higher Quality, More Affordable Health Care,” a paper by Harold D. Miller of the Center for Healthcare Quality & Payment Reform available at www.paymentreform.org.

Partial Capitation

Shared savings alone do not assist practices with upfront costs nor provide assurance they will recover these investments. Therefore, transitional models like partial capitation are needed. Under a partial capitation payment model, an ACO would agree to accept a pre-defined monthly per-patient payment during a multi-year period that would be used to cover all of the costs of care for a defined group of patients or for certain services. This type of model could be broadly defined to exclude all Part A services so that only professional services are capitated, or narrowly defined to exclude particular services like transplants. Partial capitation should provide flexibility for ACOs to define the “part” that is included in the capitation payment.

Also, under this model, the payment would be risk-adjusted and would be lower than what CMS would project paying for those patients under the regular Part A and B payment schedules. This model would enable physician practices with experience in successfully managing capitation

contracts under Medicare Advantage and commercial insurance, such as North Texas Specialty Physicians and the Mount Auburn Cambridge Independent Practice Association (IPA), to deliver better care to Medicare fee-for-service beneficiaries as well as guarantee savings to the Medicare program. Additionally, it would provide a means for practices to recoup their upfront investments, reward physicians for achieving savings through a particular treatment delivery, and permit them to gain experience managing risk.

Virtual Partial Capitation

A variant of the model above would define a per-patient budget for a defined group of patients instead of making an upfront payment. Individual physicians who volunteer to participate would bill for individual services as they will do in the Medicare ACO Program. The total billings would then be compared to the budget, and the payments to the physicians and other providers in the ACO would be adjusted up or down to keep total payments within the budget. This approach gives physicians the flexibility to use alternative treatment approaches, as in capitation, without requiring them to have the capability to pay claims to other providers.

Condition-Specific Capitation

This model would involve making a prospective payment covering all of the services related to a particular condition or combination of conditions for a population of patients, rather than the full range of conditions as in the partial capitation model described earlier. Under condition-specific capitation, a specialty physician practice, multi-specialty group, or IPA would be paid a pre-defined amount to cover the costs of all of the care needed to address a particular condition, whether that care is provided by physicians in the organization receiving the payment or other physicians. For example, a multi-specialty group or IPA could be paid a fixed amount to cover the costs of all services associated with care related to its patients with congestive heart failure, including all physician services, hospital care, rehabilitation, etc. (This payment model could also be structured as a “virtual” payment or budget, as described above for virtual partial capitation.) This would enable primary care and specialty physician practices to work together to take accountability for the subset of patients and patient care they felt they could most effectively manage. Over time, they could expand to additional types of patients in order to accept a broader partial capitation payment.

Accountable Medical Home

In contrast with the shared savings approach to medical homes, the accountable medical home model would give a primary care practice, multi-specialty group, or IPA the upfront resources needed to restructure the way primary care is delivered to its patients in return for a commitment to reduce the rate at which those patients use emergency rooms for non-urgent visits, are admitted and readmitted to the hospital for ambulatory care sensitive conditions, and order diagnostic tests or other ancillary services that may be inappropriate. Accountable medical homes could improve patient care and achieve savings for the Medicare program in several key areas without being penalized for the costs of specialized services they are not in a position to

control. In the State of Washington, the Puget Sound Health Alliance and the Washington State Health Care Authority are currently putting this model in place for commercial payers and Medicaid plans. CMS could use the approach they have developed in the Medicare program.

Warranties for Inpatient Care

Adoption of a model like Geisinger Health System's ProvenCare could be a beneficial transitional model for Medicare payment reform. Physicians and hospitals providing treatment for specified conditions would determine a Medicare payment rate that would allow them to offer a warranty for the inpatient treatment and not charge more for addressing infections, complications, or other defined adverse events that may occur during the course of the patient's care. Offering such a warranty provides an economic incentive for improving quality and preventing complications from occurring. As quality improves over time and rates of warranted complications diminish, physicians and hospitals will be able to reduce the bundled payment rate to save money for Medicare while still obtaining higher margins on their own operating costs. At least initially, the price of a warranted service is likely to be higher than what Medicare pays for a service with no complications because of the need to cover the costs of treating complications that will arise in a certain number of cases. However, since Medicare would no longer be paying separately for the complications covered by the warranty, this method would save money for Medicare in total. In contrast to the current payment system, this would reward physicians and hospitals for preventing complications and delivering better quality care rather than paying more when complications arise. Most consumer products that are sold with a warranty do cost more than those without a warranty. Consumers purchase warranted products not only as a protection against costly repairs but also because they know that the manufacturer must offer a high-quality product in order to manage its own financial risks. The warranty model is also a good transitional model because, as Geisinger did, physicians could begin with one service, like cardiac surgery, and then expand it to other areas as they gain experience with the approach.

BENEFICIARY ASSIGNMENT

The AMA urges CMS to adopt a more flexible approach to beneficiary assignment to an ACO. On a continuum from prospective, voluntary assignment, as the AMA has proposed, to a completely rigid, statistical formula driven, retrospective process, the current CMS proposal is at the extreme, latter end of the continuum. We urge that instead of retrospective attribution, CMS should adopt a prospective approach that allows patients to volunteer to be part of the ACO and permits the ACOs to know up-front those beneficiaries for whom the ACO will be responsible. Alternatively, at a minimum, we urge CMS to move further down the continuum toward some hybrid approach between prospective assignment and retrospective attribution.

Retrospective Assignment

CMS is proposing a retrospective assignment of beneficiaries after a one-year performance period. Under this approach, although the agency would provide upfront data on a set of

beneficiaries who might ultimately be assigned to the ACO, the beneficiaries for whom the ACO would actually be accountable would only be determined 12-24 months after services were actually delivered.

The AMA has recommended to CMS that patient assignment to ACOs be based on voluntary agreements between patients and their physicians, not done retrospectively through a mechanical formula. **We reiterate this recommendation, or at a minimum, we urge CMS to provide greater flexibility for patients and their physicians in the assignment process than is available in the completely claims-data-driven process that is proposed.**

The core of any successful effort to reduce costs and improve quality in health care is a strong patient-physician relationship. This, in turn, is founded in a voluntary choice by both the patient and physician to begin and maintain that relationship. CMS should seek to encourage and reinforce such voluntary relationships between Medicare beneficiaries and physicians, not weaken them or create substitutes for them.

The proposed method for assigning patients to physicians puts CMS in the position of deciding which patients and physicians have a relationship, rather than having that decision made by the physicians and patients themselves. Under retrospective assignment, neither the patient nor the physician initially knows that CMS is assigning accountability to the physician for the costs of all of the patient's care until after the fact. It will also be difficult for the physician or patient to informally ascertain whether a patient might retrospectively be assigned to a particular ACO. The median Medicare beneficiary sees two primary care physicians and five specialists working in four different practices each year. Medicare patients with diabetes see eight physicians in five practices and the median beneficiary with cardiac disease sees ten physicians in six practices (Pham et al., *NEJM* 2007). Clearly, it is not only more fair and effective, but also much more reliable to assign patients to an ACO based on a clear choice by the patient to be part of an ACO physician's panel.

Further, to make matters worse, patients are allowed to opt out of having their data provided to the ACO, but the ACO is not allowed to opt out of accountability for the costs of patients who refuse to share their data. This leaves the physician and ACO without any knowledge of other services the patient may be receiving outside the ACO even if it becomes evident that a particular patient is likely to be assigned to it. This can create an undesirable incentive for ACOs to avoid providing primary care services to new Medicare patients, particularly those with high-cost conditions, since even a single visit could result in all of the beneficiary's health care costs being attributed to the ACO.

Further, without active patient support and participation, the ability of physicians to help patients improve their health, avoid unnecessary hospitalizations, and reduce the use of unnecessary and duplicative services is inherently limited. If a Medicare beneficiary is unwilling or unable to participate in efforts to better coordinate and manage their care, then an ACO should not be held accountable for the overall costs of services associated with a beneficiary simply because a primary care physician in that ACO provided the beneficiary with a requisite threshold of

primary care services (and, as a result, is assigned to the ACO). Conversely, if a beneficiary and a physician mutually agree to work together to provide high-quality care for the beneficiary's most critical needs, the ACO with which the physician is associated should not have any savings resulting from that care attributed to other providers based on an arbitrary statistical rule.

Consequently, CMS should seek to maximize the extent to which an ACO is held accountable only for those patients who voluntarily choose its physicians to provide or manage their care, and who are willing to allow the ACO to access data about the patients' services. It should also seek to minimize or eliminate the use of statistical attribution methodologies, particularly retrospective attribution, after care has already been delivered. At a minimum, CMS should create one payment option that allows beneficiaries to elect participation in an ACO and makes ACO-related payments based only on the beneficiaries who make that election.

It is important to recognize that prospective *choice* of an ACO by a beneficiary is different than prospective *assignment* of the beneficiary to the ACO using statistical methodologies. In the preamble to the proposed regulation, CMS only examined two options: (1) prospective assignment using statistical methods; and (2) retrospective assignment. CMS did not examine, however a third option of prospective choice by the beneficiary to participate in the ACO. Although CMS has expressed concern that prospective assignment methodologies would encourage ACOs to treat assigned patients differently than unassigned patients, the whole goal of creating ACOs is to change the way care is delivered to patients in the ACO. If a patient wishes to benefit from the improved care coordination services offered by an ACO, then the patient needs to actively support and participate in that care. It is unreasonable for CMS to expect an ACO to change the way it delivers care for all Medicare beneficiaries, but only to be paid differently for a subset of them.

Patient Education and ACO Marketing Materials

Proactive efforts are critical to educate and encourage beneficiaries to take actions that will help make ACOs successful, e.g., to choose and consistently use a primary care physician as a medical home, select specialty physicians, hospitals, and other providers that coordinate effectively with their primary care medical home and each other, engage in shared decision-making processes with their physicians about appropriate treatments for their conditions, and participate in other types of programs developed by their physicians that can maintain and improve their health at an affordable cost. The Institute of Medicine has been working with a multi-stakeholder group, including the AMA, to develop guidance for such an initiative. Education efforts should be developed in cooperation with physicians and launched as soon as possible, and well in advance of the initiation of the ACO program on January 1, 2012.

Further, the requirement that CMS approve all ACO marketing materials is an unprecedented, unnecessary, inappropriate, and unworkable requirement. If CMS feels it needs to control the content of ACO marketing materials, the agency should define the standards for what is to be included or excluded in the regulations, and allow ACOs to implement those standards. In the

absence of such standards, and with a requirement for review and approval by CMS, ACOs will likely experience long delays in having documents reviewed, as well as incur high costs for what may be minor revisions, and there will likely be inconsistencies in what CMS approves depending on when the documents are submitted.

Provision of Beneficiary Data

CMS, in an effort to offset the uncertainty of its retrospective beneficiary assignment approach, proposes to prospectively provide ACO providers with aggregated data reports for potentially assigned beneficiaries. This data will include certain identifiable beneficiary information at the beginning of the performance year, including name, date-of-birth, gender, and Health Insurance Claim Number (HIC) of the historically assigned population. At an ACO's request, CMS will provide certain identifiable claims data on a monthly basis in standardized format, including Parts A, B and D data, to assist in care coordination efforts. Minimum data would include: procedure code, diagnosis code, beneficiary ID, date-of-birth, gender, and, if applicable, date of death, claim ID, form and thru dates of service, provider or supplier ID, and claim payment type. Part D data would include prescriber ID, drug service date, and an indication if the drug is on the formulary.

While we strongly endorse having CMS provide detailed data to ACOs on their patients as frequently as possible, we want to emphasize that the mere provision of data is not a substitute for voluntary assignment of patients. Indeed, under the regulations as written, CMS would be providing ACOs data on some beneficiaries who would not ultimately be assigned to them (since the actual assignment would occur based on all claims data during the performance year, whereas the claims data provided to the ACO would only be for patients assigned to the ACO during the prior year), and CMS would not be providing the ACO with data on some patients that would ultimately be assigned to them. Since studies have shown that on average, about one-third of Medicare patients are attributed to a different physician each year than in the prior year (Pham et al., *NEJM* 2007), this mismatch would represent a serious problem for an ACO's ability to effectively manage costs, particularly if it is being held accountable for cost increases.

In addition, it is unreasonable for CMS to only provide an ACO with data on potentially assigned patients after the contract begins. Prospective ACOs need data immediately – well in advance of signing a contract with CMS, in order to identify both opportunities to reduce costs and areas of potential cost increases that could reduce savings or trigger payment penalties.

Further, the AMA is concerned that CMS may not have the technological systems and other resources in place to provide data that is timely, relevant, and comprehensive enough to help manage care and risk. Experience with the Physician Quality Reporting System (PQRS) underscores our concerns with CMS' data capabilities. Under this program, CMS has not been able to provide timely feedback reports. Rather, these reports have been issued well after the reporting period, at which time their value is very limited. On the other hand, a "data dump," without identifying the relevant data, would not be a viable alternative either. The data reports

must show how the data relates to the ACO's benchmark, and cannot simply be raw data. Moreover, the data must be standardized, which is critical for physicians that may participate in more than one ACO.

Plurality of Primary Care Services

Under the CMS proposal, beneficiaries will be assigned to an ACO based on receiving a plurality of their primary care from primary care physicians within that ACO. Primary care physicians are those with specialization in general practice, family practice, internal medicine, and geriatrics.

As noted earlier, the AMA believes that voluntary assignment should be used, rather than any statistical attribution formula. However, if a formula is to be used, the AMA is concerned that beneficiary assignment based on a plurality of primary care services from a primary care physician over the course of a year could result in a large proportion of patients being assigned to a physician who is not the patient's current primary care physician. For example, if a beneficiary has been seeing one primary care physician for some period of time and then switches to a new primary care physician part of the way through the year, the attribution model would assign the patient to the former physician for that year even though the patient was now being managed by the new physician. Because CMS is proposing to use a three-year average to make the assignment, it could take over a year before the statistical rule assigns the beneficiary to the correct physician.

In addition to this problem, beneficiaries with multiple chronic conditions often receive a plurality of their care, including a plurality of primary care services, from physicians who are not "primary care" physicians, as defined in the proposed rule. The same is often true for patients in rural areas as well. In these cases, the patient may be assigned to a physician practice or ACO which has a primary care physician that the patient happened to see during the prior three years, even though the patient is actually receiving the majority of their primary care services from a non-primary care physician in a different practice or ACO. These patients should be assigned to the non-primary care physicians who furnish the plurality of the primary care services. **This problem would not occur if the patients affirmatively selected their ACO. If, however, CMS uses statistical attribution methodologies, it should expand the "plurality of care" proposal to primary care services delivered by any physician, not just certain "primary care physicians."**

Primary Care Physician Exclusivity

Primary care physicians for which beneficiary assignment is made must be exclusive to one ACO for the three-year period. Providers which assignment is not dependent on (*i.e.*, specialists, hospitals, rural health clinics and federally qualified health centers) can participate in more than one ACO. CMS also considered a two-step option that would count primary care provided by specialists if an ACO's primary care physicians did not meet the 5,000 patient threshold. These specialists then would also be limited to just one ACO.

The AMA urges CMS to allow primary care physicians, including any specialists whose primary care services are counted toward the threshold, to participate in more than one ACO.

Limiting primary care physicians (and specialists whose primary care services are counted toward the threshold) to only one ACO could discourage these physicians from participating and reduce the number of ACOs that can form in a particular community. Family physicians and other primary care physicians often provide health care services to many Medicare patients across a broad geographic area or that receive further care in multiple tertiary centers and various hospitals. Moreover, because of the way some private health plans structure their coverage, a physician may have to participate in multiple separate networks of physicians and hospitals in order to have all of their patients covered by insurance. By locking primary care physician participation into only one Medicare ACO, CMS essentially is limiting ACO participation to only a portion of the primary care practice's Medicare patient population.

We recognize that if CMS assigns beneficiaries to a specific ACO based on their utilization of primary care services, and if the primary care physician participates in two ACOs, there could be confusion over the ACO to which the patient should be assigned. Prospective and voluntary assignment, however, would avoid this problem.

Beneficiary Choice of Physician

CMS states in the proposed rule, at 76 *Fed. Reg.* 19,567, that if a beneficiary's physician becomes part of an ACO and the beneficiary does not wish to receive health care services under the ACO care coordination and management efforts, the beneficiary has the freedom of choice to go to a different physician. The AMA does not believe that this is true "free choice" for patients. If a beneficiary has maintained a particular physician for a number of years or even decades, but does not want to participate in the ACO network, this beneficiary should not be required to switch to a new physician. This could present serious continuity of care problems for patients, especially those with chronic conditions. It could also be extremely detrimental to the physician's practice, which could lose a substantial number of patients who are confused or concerned about what participation in the ACO could mean for their care. **The AMA, therefore, urges CMS to allow patients to affirmatively opt out of being part of an ACO while still maintaining their physician of choice.**

QUALITY MEASURE AND OTHER REPORTING REQUIREMENTS

We urge CMS to: (1) align quality measure domains and quality measures across its programs (including the ACO, Electronic Health Record (HER) Incentive Program, and PQRS) and reduce the number of required measures in the initial years; (2) provide ACOs with some flexibility of measure selection; (3) reconsider data submission methods; and (4) support clinical quality registries as a significant data submission method.

Quality Domains and Measures Flexibility

To assess the quality of care furnished by an ACO, CMS is proposing certain quality measures for which ACOs must report data. Specifically, CMS is proposing 65 measures for use in calculating an ACO's quality performance standard across five key domains: patient/caregiver experience; care coordination; patient safety; preventive health, and at-risk populations/elderly. Thirty of these measures are PQRs measures, 28 are new measures—either National Quality Forum (NQF) endorsed and/or CMS-adopted, 26 are from the EHR Meaningful Use program, and one incorporates the nine hospital acquired conditions.

In the ACO's first year of operation, CMS has proposed that ACO providers are required to successfully report on the required measures. In years two and three, the ACO will be evaluated on its performance on these measures. There will be a performance threshold calculated based on the ACOs measurement scores. 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.

We agree with CMS that it is useful to identify measure domains to provide focus and clarity of purpose of selected measures. We also agree with CMS's intent to evolve a focused set of measures appropriate to each specific provider category. Therefore, we suggest that similar to the approach for Stage I of the EHR Incentive Program, CMS offer a menu of measures, all emphasizing the domains, from which ACOs can select to build a portfolio of measures that best reflects their patient populations while also enabling regional and national benchmarking.

Specifically, we urge CMS to:

- 1. Reduce the number of measures within patient/caregiver experience, care coordination, patient safety and preventive health to represent more of an “initial core” on which to build (similar to EHR Incentive Program).**
- 2. Lay out a glidepath for measures for at-risk population/frail elderly to emphasize that measures sets for clinical areas (e.g., heart failure) should eventually include measures in several domains, such as patient/family engagement and clinical effectiveness. Further, CMS should begin to identify measures for each clinical area within those domains.**
- 3. Permit ACOs to report on the “core” plus four of the six clinical sets most relevant for their patient populations.**

Reporting Data on Quality Measures

The AMA urges CMS to consider alternative approaches to the quality reporting requirements to allow ACOs and all stakeholders involved more lead time as they evaluate and plan to meet the requirements of a new program. First, instead of an all-or-nothing approach to reporting data on quality measures, we recommend a more flexible approach allowing ACOs to submit to CMS a plan for reporting on quality measures. A menu of

quality measures would be available from which ACOs could choose, including a number of standard national measures that apply across all ACOs (e.g., care transitions, drug-related and other adverse events, and functional status), as well as measures that an ACO could choose that are applicable to their core patient population. This will allow ACOs to choose measures that are the most relevant to the patient population they treat. For example, ACOs in communities where Regional Health Improvement Collaboratives have established public quality measurement and reporting programs should be permitted to use the measures defined in those programs and to rely on the quality reports generated by those programs to meet CMS's requirements.

Moreover, in choosing among national measures, we urge CMS to use existing quality measures that are in use in other CMS programs, such as the PQRS, since stakeholders already have processes in place to gather this data, as well as experience with these measures. This will help avoid unforeseen challenges with measures that have not been evaluated or used in national programs.

Although additional quality measures may ultimately be warranted, it is impractical to develop a single national set of such measures prior to implementation of the ACO program, as the areas where ACOs will focus their quality improvement strategies and cost reduction strategies will likely vary significantly from ACO to ACO, and measures that may be appropriate for one ACO model may not be appropriate for another. Therefore, as discussed above, ACOs should be allowed to report on a hybrid of national and local quality measures related to their particular patient population to facilitate implementation of strategies that will improve care and reduce costs. At this early stage, when there is so much we do not yet know about ACOs, a one-size-fits-all approach would be too restrictive.

Further, the AMA believes that initially, 65 measures are too many, as these measures will require special different data sources and reporting processes to gather and submit the data. Again, the ACO program is in its infancy, and it is not prudent to create such a high reporting burden that some physicians who have the potential to form successful ACOs are deterred from participating in because of the high reporting burden, or fail to succeed because of that burden. **We urge CMS to lower the number of measures for which ACOs would be required to report data in the first few years of the program.**

The AMA is also concerned that a requirement to meet all 65 measures will effectively require participation of a hospital in the ACO. For example, to measure the performance of an ACO with regard to patient safety, the regulation proposes to use the nine hospital-acquired conditions currently included in the Medicare Inpatient Hospital Acquired Conditions Non-Payment Program. Hospital readmission measures are also required. It is difficult to conceive how an ACO will readily have access to this information unless a hospital is part of the ACO. Further, the type of interoperability needed to transfer data from a hospital to independent physician practices that form an ACO is not yet widely available. Further, if a hospital is experiencing reduced admissions and revenue due to the success of an ACO that does not involve the hospital, the hospital will have little incentive to provide the ACO with the measurement data necessary to

achieve success. In addition, patients in most communities have a choice of more than one hospital. Even if an ACO does include a hospital and is able to report on hospital-acquired conditions for its patients who go to that hospital, the information is unlikely to be available for all the other hospitals patients may use.

Finally, CMS says in the proposed rule that it will publish measure specifications for the required quality measures before the January 1, 2012 effective date of the ACO program. **We urge CMS to publish these measure specifications as soon as possible, and at least 90 days in advance for 2012, so that ACOs can get the specifications and be adequately prepared to begin operations immediately. For subsequent program years, we recommend that CMS publish measure specifications 180 days in advance.**

Program Alignment

The AMA urges that CMS work to align the rulemaking, implementation, and reporting rules of the ACO, PQRS, and EHR incentive programs. Many of the same measures are in the PQRS, EHR Incentive program, and now are proposed for the ACO program. However, due to differences in reporting requirements, a physician must go through separate reporting processes to report on the same measure for the PQRS, ACO, and EHR Incentive programs. Therefore, data collection and quality measurement for physicians is unnecessarily burdensome and duplicative.

We also urge CMS to exercise flexibility to ensure the most updated version of measures are included in their programs. Specifically, if an updated measure is in, or awaiting, the National Quality Forum (NQF) Maintenance of Endorsement Process, and the NQF timelines are not matching CMS' timelines, the agency (and its contractors) should use the most recent measures specs, as recommended by the measure developer. For example, the PCPI has retired the "Weight Measurement" measure from its Heart Failure set, and recommends that this measure not be included in future CMS programs. Additionally, in the PCPI update to the CAD measurement set, the CAD-Beta-Blocker Therapy—Prior Myocardial Infarction (MI) measure now includes patients with Left Ventricular Systolic Dysfunction (LVEF <40%). To ensure CMS programs include measures that reflect the latest evidence, the most recent versions maintained by the various measure developers should be incorporated into the programs. The PCPI can direct CMS and its contractors to the most recent measures during weekly calls with CMS and measures stewards whose measures are included in CMS programs.

The AMA further urges that CMS look to processes that have been established for the PQRS with respect to communication between measure developers and CMS-designated contractors, and apply these to newer CMS programs, such as the ACO program. Measure developers, in particular the PCPI, have worked collaboratively with CMS contractors since 2007 to develop and maintain the specifications for quality measures included in CMS programs.

Group Practice Reporting Option

The Group Practice Reporting Option (GPRO) data collection tool is referenced in the proposed rule as a potential data submission mechanism for the ACO program. **The AMA urges that the information used to calculate the measures is transparent to both the ACOs and the measure stewards whose quality measures are included in the program.** This level of transparency is important in order to ensure that the ACOs understand how performance rates are being calculated, and that measure stewards can validate that the measures are being applied in a manner consistent with the measure's intent.

Registries

The AMA urges CMS to outline a glide path to encourage participation in and measure submission to disease registries. These registries have demonstrated value in improving the quality and safety of care, and evaluating efficiency and cost effectiveness. In addition, disease registries provide timely feedback to providers for benchmarking and identification and adoption of best practices.

Performance Thresholds

Under the rule, as discussed above, CMS proposes that in the first year the quality performance threshold standard is based on 100 percent complete and accurate reporting on all quality measures, but does not set forth such performance threshold for years two and three. CMS plans to specify the quality performance standard for these later years. **We look forward to further guidance and commenting on the performance threshold for years two and three. There is some confusion in the proposed rule concerning these thresholds, and we look forward to further clarification.**

For the first year, however, CMS is proposing 100 percent reporting on all measures before an ACO is eligible to share in any savings. The AMA urges CMS to apply more flexibility to this requirement. CMS should allow ACOs that achieve savings to share in some percentage of the savings even if the ACO has not successfully achieved performance thresholds on all 65 measures. We know from experience with initial PQRS program years that errors can occur with the capture, transmission, and evaluation of quality measurement data. For example, under the 2007 PQRS program, backlogs in processing physician National Provider Identifiers (NPIs), a faulty process for determining measure applicability to certain physicians, and Medicare carrier error in processing quality data codes, inadvertently prevented some physicians from successfully reporting. Moreover, individual PQRS feedback reports continue to be issued long after the reporting period, causing physicians to unknowingly report incorrectly well into the next reporting period.

Since the ACO program is new, similar unforeseen glitches out of the ACO's control are likely to arise, unfairly resulting in an unsuccessful quality reporting determination. In addition, there may be circumstances when an ACO may erroneously report on one or a few measures, or the ACO may not have the data to successfully report on other measures, especially when the ACO has to obtain this data from another entity, such as a competing hospital. It would be draconian in any of these instances to bar the ACO from sharing in any savings, especially if an ACO has successfully improved quality and efficiency and created significant savings for the Medicare program.

Beneficiary Experience of Care Survey

The AMA has long encouraged physicians to measure their patients' satisfaction and knows the value this data can bring to a practice. Patient experience data can help a physician identify opportunities for quality improvement and ultimately better run their practice. Feedback from the patient experience surveys can also improve physicians' ability to care for their patients, potentially improving their patients' health and compliance. Collecting this data is particularly important for ACOs, as they face growing pains that could impact their patients' experiences. However, collecting such data is also expensive, and CMS needs to provide financial support to ACOs if it requires specific data or methods of data collection that go beyond what physician practices are already doing.

Survey and Survey Tool Options

CMS has requested input on whether it should require ACOs to use a specific survey and survey tool or allow ACOs to use, or adopt, a survey and survey tool of their choice.

There are a number of different surveying tools available to physicians, and many physicians have already chosen the tool that best meets their needs. It often takes time for a practice to determine the best tool for its physician(s) and become adept at reading and interpreting the reports to discern opportunities for practice improvement. Requiring practices to move to a new survey tool could be very disruptive and burdensome. Those practices that have already adopted patient experience tools are doing so to better meet their patients' needs and are clearly interested in quality improvement.

The AMA recognizes the importance of benchmarking and internal evaluations however, and supports the need for all members of an ACO to use a uniform survey and survey process. We further appreciate the need for some standardization in the use of survey tools across ACOs so that accurate comparisons can be made. Therefore, in addition to some standardization in the patient experience survey tool, CMS should allow flexibility for ACOs to use their own experience in developing a patient experience tool that addresses the particular needs of that ACO and its patient population. For example, a survey tool should provide physicians with the flexibility to swap questions that are no longer relevant to their practice with questions that target areas in which they want additional feedback. CMS should also test on a wide scale basis the use of patient experience surveys in a clinical setting.

Further, in establishing a survey tool, we urge CMS to take into account the following:

- **Electronic data collection is a cost-effective, easy to administer, and powerful method for to collecting patient satisfaction data. The AMA strongly encourages CMS to permit ACOs to use survey tools that collect data in this manner. Electronic survey results are received in a timely fashion and usually there is little administrative burden on the practice.**
- **There are a number of patient experience surveys available to physicians, and the AMA believes the best surveys provide actionable feedback to physicians. The proposed rule suggests that the CG-CAHPS survey specifically may be the required instrument for ACOs. While the AMA continues to support the use of the CG-CAHPS survey as a means of measuring the patient centricity of a medical practice, we are concerned about the possible exclusivity of its use when there are other survey instruments that may provide more actionable feedback to the physician practice. Further, we are concerned that some of the CG-CAHPS questions are not directly related to behaviors that a physician or their staff can change, and, as a result, the data may still leave a practice wondering what steps it can take to improve. Requiring the use of CG-CAHPS only would not allow physician practices any flexibility in the survey process.**
- **Survey instruments approved by CMS for ACO use should be based on visit-specific questions, rather than one year collective and retrospective questions.** Visit-specific responses are infinitely more useful to practices than data that looks back over 12 months. The primary goal of collecting patient experience data is to use it for quality improvement, and more current data can have the greatest impact in terms of focusing the practice on the current needs of its patients. Additionally, it is difficult for some patients to collectively remember the details of potentially multiple physician visits. This problem is further exacerbated when multiple visits result in the patient having to coalesce differing levels of satisfaction per visit into one combined rating. Finally, when a practice makes changes in an effort to better meet the needs of its patients, it is important for the practice to be able to track and evaluate the results of those changes from the patient perspective over the course of their visits.

The AMA Patient Experience Survey

The AMA has collaborated with Press Ganey to develop a patient satisfaction survey product that brings together the combined resources and experience of the country's largest physician member organization with the patient experience survey company most used by hospitals and physicians. The survey itself is approximately 25 basic questions, including several of the non-retrospective CG-CAHPS questions. The remaining questions on the survey are behaviorally oriented to garner actionable results. A set of demographic questions are also included for analysis and cross-tabs to allow physicians to improve their practice by understanding their patient mix, and, in turn, their patients' experiences. After six-months, physicians can begin to

customize the survey, adding questions that provide additional information in areas in which the practice would like to improve.

The product uses email as the primary method of survey distribution, and data is collected electronically in real-time. We have found that delivering the survey via email is extremely effective and, in a pilot program conducted last year, we regularly saw average adjusted response rates of nearly 50 percent. The electronic method generates credible sample sizes on a quarterly and often monthly basis, which helps providers and staff fully relate to their performance scores, take immediate action and continuously track the effectiveness of their improvement efforts. Not everyone has an email address or access to a computer, and, as a result, the responding population to an electronic survey could vary by demographic. We also recognize that some practices with unique patient populations, such as those with a large number of elderly patients or patients with significant disabilities, may not feel as comfortable using exclusively electronic surveying. In these situations, mail surveys, kiosks, or even phone surveys, could be used to collect feedback from these patients, as well as any patients from demographic backgrounds that are under-represented in the electronic survey results.

The system compiles the results of the electronic and optional paper surveys as soon as each patient completes a survey and all comments are reported within minutes of being entered. Scaled responses are available for review by the next business morning. Data may be viewed by physician, site (practice location), specialty, or group. Reports are customizable at the individual user level, meaning each user can view current and trended data for any user-defined time period or reporting group desired.

The AMA is also using the survey tool as an opportunity to help practices with their quality improvement efforts. This survey tool can work with the most basic practice management systems or the most sophisticated, and is cost-effective enough to appeal to small and large practices alike.

Public Reporting

CMS is proposing that ACOs publicly report certain information, including information relating to ACO participants, ACO joint venture arrangements and other organizational information, shared savings, and quality performance standard scores. CMS proposes that each ACO has the responsibility for making this information public in a standardized format that CMS will make available through subregulatory guidance. CMS requests comments on these proposals.

The AMA agrees with CMS' proposal that ACOs themselves would be required to make this information publicly available, rather than reporting the information to CMS to make publicly available, and we urge CMS to maintain this proposal. We also urge that ACOs have the opportunity to review and verify the data CMS uses in developing performance standard scores before this data is required to be made public. This will give ACOs the ability to maintain, update, comment on, and modify their own reporting system, which will be

very important as the ACO gains experience in how best to respond to patients and ACO participants for purposes of making this information relevant, timely, and actionable.

We also understand CMS' proposal to use a standardized format for reporting the information so that information is comparable across ACOs. Yet, when CMS provides further subregulatory guidance on this matter, it is critical that CMS balance the standardization requirement with a need for flexibility for ACOs to respond to the particular needs of its patients and other stakeholders at a local and individual organizational level. **While some key information could be standardized, ACOs should have the flexibility to report information in a manner that is unique to that ACO as well.**

This flexibility for ACOs is essential because public reporting of performance information, if not approached thoughtfully, can have unintentional adverse consequences for patients. For example, patient de-selection can occur for individuals at higher-risk for illness due to age, diagnosis, severity of illness, multiple co-morbidities, or economic and cultural characteristics that make them less adherent with established protocols. Health literacy may not be adequate to comprehend basic medical information, and programs must be designed so that appropriate and accurate information is available to patients to enable them to make educated decisions about their health care needs. If done correctly, public reporting has the potential to help provide such appropriate and accurate information to patients. **If ACOs are responsible for making performance standard scores publicly available, and have the flexibility to meet its patients needs, this can help avoid unintentional adverse consequences for patients.**

Further, the AMA does not believe CMS should consider public reporting in the ACO program at the individual physician level until there is ample opportunity to learn from the initial years of the program. Further, key issues must also be addressed, such as adequate risk adjustment, correct attribution, the need for accurate, user-friendly, relevant and helpful information for patients and other affected stakeholders, physician verification of data, along with the opportunity for prior review and comment and the right to appeal with regard to any data that is part of the public review process. Any such comments should also be included with any publicly reported data. This is necessary to give an accurate and complete picture of what is otherwise only a snapshot, and possibly skewed, view of the patient care provided by physicians and other professionals or providers involved in the patient's care.

Physicians' ability to review, correct, and comment on patient experience survey results prior to final evaluation and public release is particularly critical because these types of surveys are based on people's perceptions, are inherently subject to people's prejudices, memories, and even visit outcomes not related to the physician or practice. A patient who received a poor diagnosis may remember a physician visit quite differently than a patient who received a clean bill of health. Therefore, temperance is required in the use of such results that could impact a physician's reputation and compensation.

Electronic Health Records Technology Requirement

The AMA does not support CMS' proposal to require that at least 50 percent of an ACO's primary care physicians must be using certified EHR technology and be "meaningful EHR users" by year two of the ACO Program in order to continue participation in the Shared Savings program. Merely having an EHR (even if it is being used "meaningfully") does not guarantee improved care or care coordination, nor is it necessary to have an EHR in order to improve care or care coordination. Moreover, it is premature to impose such a high percentage threshold in the ACO program. **The EHR meaningful use incentive program was just launched in January 1, 2011, and has not yet been thoroughly assessed. ACOs should have the flexibility to come up with their own percentage requirements for meeting EHR meaningful use measures.**

CMS should first survey physicians who elect to participate and those who elect not to participate during Stage 1 of the Medicare/Medicaid EHR meaningful use incentive program to assess whether the Stage 1 requirements are reasonable and achievable for most primary care physicians. In addition, CMS and the Office of the National Coordinator (ONC) should evaluate the usability of existing certified EHR products, and survey physicians on how well these products aid physicians in delivering quality of care, enhancing patient safety, supporting practice efficiencies, as well as meeting meaningful use requirements. **The results of CMS and ONC evaluations of the EHR products and the meaningful use incentive program requirements need to be considered *prior to imposing a high percentage requirement for meeting meaningful use measures in the ACO program.***

It is important to keep in mind that for Stage 1 of the EHR incentive program, eligible primary care physicians have to meet a total of 20 meaningful use measures (15 core measures and select five measures from a menu set). If a physician is unable to meet just one out of the 20 measures during the reporting period, s/he would not be a meaningful user under the incentive program. If the Stage 1 EHR meaningful use requirements are determined to be too burdensome for many primary care physicians, the primary care physician participation in the ACO program would be limited and adversely impacted. Primary care physicians are key participants for ensuring the success of ACOs, and the program requirements should encourage their involvement not discourage them. In addition, Stage 2 and 3 measures for the Medicare/Medicaid EHR meaningful use incentive program have not yet been proposed. It is unrealistic to expect that at least 50 percent of primary care physicians participating in an ACO would be able to meet Stage 2 and 3 meaningful use requirements that have yet to be proposed. Committing that at least 50 percent of an ACO's primary care physicians would be "meaningful EHR users" by year two of the ACO Program would be a very risky venture for an ACO given the many unknowns associated with successfully meeting the meaningful use program requirements. Moreover, the ACO proposed rule indicates that CMS has the right to terminate an ACO agreement if fewer than 50 percent of an ACO's primary care physicians are not meaningful EHR users. **We do not support CMS' proposal to use the meaningful use EHR incentive program as a grounds to terminate an ACO agreement.**

The goal for a participating ACO is to improve care for patients and achieve shared savings for Medicare. ACOs should have the latitude to make the investments in technology, programs, and services for their defined population that maximize their chances of achieving this goal. An example would be the use of disease management programs for chronic disease patients. Given the demographics of the Medicare population, an investment in such a service might have a greater impact than investments that would be required to meet the 50 percent target for meaningful users of EHRs. **CMS should welcome variation among ACOs in finding the most cost-effective means for achieving savings.**

Physicians are diligently working towards incorporating well-developed EHRs into their practices to improve quality of care delivery, enhance patient safety, as well as support practice efficiencies. Purchasing, implementing, and maintaining EHR systems is very expensive, particularly for small physician practices. Consequently, making the acquisition, implementation, and meaningful use of such systems a requirement for 50 percent of ACO primary care physician participants by the start of year two of the ACO Program could deter many small practices from participating in an ACO. This runs counter to one of the main goals of CMS' ACO Program proposal—to not disadvantage solo and small groups of physicians from participating.

Encouraging greater development and use of health information exchange (HIE) is also essential to supporting the goals of meaningful use. Health care partners must be capable of exchanging the requisite data and that data must be presented in a way that is understandable to the physician. Until the national, regional, and local infrastructures have been substantially developed and tested to allow for the secure electronic exchange of patient health information, the percentage requirements should remain low for meeting measures that still can only be met through manual data entry.

Until we are able to develop robust bidirectional health information exchanges and ensure that the Medicare/Medicaid EHR meaningful use requirements for Stages 1-3 are realistic and achievable for most primary care physicians, the ACO requirements should not be so prescriptive as to require such a high percentage of ACO primary care physicians to meet the meaningful use EHR incentive program requirements. **The AMA strongly recommends that ACOs should have the flexibility to come up with their own percentage requirements for meeting EHR meaningful use measures.**

ACO GOVERNANCE STRUCTURE

CMS is proposing that ACO participants must have at least 75 percent control of the ACO's governing body. Further, each ACO participant must choose an appropriate representative from within its organization to represent them on the governing body. CMS has requested comments on whether this 75 percent threshold is an appropriate percentage. **The AMA agrees with this proposal, and we are pleased that the regulations require a significant role for physicians in the governance and management of the ACO. We urge CMS to maintain this proposal.**

We also strongly agree with CMS' proposal that the ACO's clinical management and oversight should be managed by a senior-level medical director licensed and present in the state where the ACO is located. We are generally supportive of the requirement that the medical director be board-certified. We suggest, however, that CMS may want to consider some alternatives for physicians who have not applied for re-certification by one of the members of the American Board of Medical Specialties, but has instead acquired certification in medical management or quality improvement. This might include a certificate from the American College of Physician Executives Certifying Commission on Medical Management, as well as the American College of Medical Quality's certification in quality. Physicians who have focused on public health and have Masters in Public Health degrees, Masters in Medical Management, or Masters in Health Care Administration, and appropriate experience, should also be considered.

RURAL HEALTH CLINICS

The AMA is very concerned that CMS has structured the ACO in a manner that excludes rural health clinics, and we urge CMS to develop a path for rural health clinics to be ACO participants. We do not believe that Congress intended for rural health clinics to be largely left out of the ACO program, and it is critical that these clinics be part of the process since rural physicians in rural health clinics furnish a substantial amount of primary care services to patients who would benefit from ACO care management programs.

WAIVERS OF FEDERAL PROGRAM INTEGRITY LAWS

The AMA strongly supports the overall effort to propose waivers of federal program integrity laws in order to test new payment models and methods that improve patient outcomes and promote value. At the same time, we strongly urge the Office of the Inspector General of the U.S. Department of Health & Human Services (OIG) and CMS to address a number of barriers that remain in the context of federal and state program integrity laws that will inhibit or chill the development of ACOs that were not fully addressed in the proposed rule. **Further, similar to our above request for the ACO proposed rule, we urge CMS to issue an interim final rule, rather than a final rule, so that CMS maintains the flexibility to modify and improve the program integrity regulations in relation to ACOs as CMS learns more about the ACO model.**

The ACA explicitly authorizes the HHS Secretary to waive requirements under section 1128A, and 1128B, and Title XVIII of the Social Security Act that contain the Civil Monetary Penalty (CMP) statute, the federal anti-kickback statute (AKS), and the Ethics in Patient Referrals (Stark) law. The AMA previously commented that the establishment of a full range of waivers, safe harbors, and/or exceptions are needed so that the marketplace can benefit from physician-led ACO integration models. We strongly support the decision to establish waivers to Stark, AKS, and the CMP statute. We applaud the decision to extend waivers outside of the ACO for "activities necessary for" and "directly related to" the ACO's participation in and operations under the Medicare ACO Program. We support the clarification that the waivers extend to CMP

and AKS and agree that such waivers make headway toward easing the burden on entities that establish ACOs in a manner consistent with the Stark Law regulatory exceptions.

Given the new and evolving nature of ACOs, we urge the government to adopt inter-agency enforcement guidelines establishing that there is a strong presumption that activities necessary for the planning, formation, and operation of ACOs are “necessary for” and “directly related to” the ACO participation in, and operations under, the ACO Program. Similarly, we strongly recommend a similar recommendation with regard “medical necessity” in the context of the CMP statute. As with any new regulation or policy, there is concern that these standards have the potential to be evaluated in a subjective and potentially inconsistent or confusing fashion. We recommend that the government adopt internal interagency guidance and protocols that emphasize the importance of ensuring that ACO participants are afforded a meaningful opportunity to work with regulators to address any concerns without threat of substantial monetary and criminal sanctions. We are also concerned that the proposed waiver is not sufficiently broad to facilitate the kind of ACO development intended by the ACA. In light of the infusion of a substantial sum of funds into federal and state health care law enforcement efforts, we have significant concern that tools to combat program integrity threats based on the current payment model will stymie efforts to construct and transition to new payment methods.

While we are enthusiastic about the application of the waivers outside of the ACO participants in the context of the Medicare ACO Program, we urge you to expand these flexibilities to the distribution of underlying Medicare payments for service, not just shared savings. **We recommend allowing distributions—both underlying Medicare payments for service and shared savings—to providers who are not formally participants in the ACO, such as specialists. It will be a very difficult barrier to scale, if not insurmountable, if ACO participants are prohibited from working with providers outside of the ACO to improve care and meet quality performance standards, even when these activities do not generate shared savings for distribution.**

Duration of Proposed Waivers

The proposed waivers are too limited in duration and may discourage independent practicing physicians who have not already done so from developing an organization that could potentially be accepted into the shared savings program. As proposed, waivers would only be available once CMS has accepted the ACO into the ACO Program. But a great many tasks requiring significant financial resources and physician sweat equity may have to be completed prior to submitting an application to CMS. For example, physicians will have to form new and diverse financial relationships among themselves and third parties such as medical groups, independent practice associations, and hospitals in order to acquire the financial resources and other expertise necessary to determine whether or not taking affirmative steps toward ACO creation will best serve the community and otherwise make sense. This analysis will include, but not be limited to, market studies, *e.g.*, an evaluation of the ACO’s actual and potential competitors, business planning, analysis of the demographics and health status of the patient population that the ACO may serve, studies determining the optimal number and identity of the primary care physicians

and specialists that should comprise the ACO, and analyses of utilization rate for likely ACO participants across a wide range of service lines and settings with respect to beneficiaries who may be assigned to the ACO. They will likely require staff hiring or retention of consultants, and the resources for this staff or consultant expertise will likely come at least in part via new financial relationships among physicians themselves and in some cases institutional health care providers. For example, an independent practice association or a hospital might be willing to fund the lion's share of the costs of retaining consultant services on behalf of interested physicians, or provide in kind support such as training or staff to such physicians. Additionally, interested physicians might vary considerably in the amount that they personally invest in the ACO and/or receive from organizations such as an independent practice association. Unless waivers are extended to these kinds of exploratory ACO activities, many financial relationships may implicate significant fraud and abuse liability exposure.

It is also crucial that the waivers be available to financial relationships that are necessary to create the extensive infrastructure that an ACO must have in order to be accepted into the ACO Program. Again, physicians and other health care providers without the significant financial capital will have to obtain financial assistance to develop this infrastructure. Infrastructure will include, but not be limited to, mechanisms to coordinate care among ACO participants, health information technology, quality and cost data reporting systems, staff hiring, systems that will operationalize performance measurements in ACO participants' practices and allocate performance results and payments accordingly. Again, physicians may contribute at least some of the needed financial resources, but will also require financial assistance, in cash and in kind, from larger organizations. Additionally, the ACO may need to establish referral relationships between ACO participants, as well as referral relationships between ACO participants and specialists or facilities that do not participate in the ACO. The provision of this financial assistance as well as new referral relationships will inevitably create financial relationships that, absent the extension of waivers, will raise the specter of liability exposure.

The proposed waiver period should also extend beyond the termination of the three-year term of the ACO agreement. Based on the lessons learned so far from the Physician Group Practice (PGP) demonstration project, it seems likely that many ACO's will not see any shared savings within the three-year agreement period. After four years' participation in the PGP, five out of ten of some of the most integrated group practices in the country received shared savings. Lacking analogous integrative development, ACOs resulting largely from the efforts of independent practicing physicians and physician organizations, such as independent practice associations, will likely require more time to produce shared savings than the PGP participants. Accordingly, it is highly unlikely that independently practicing physicians or organizations of such physicians will seriously consider investing the \$1.7 million that CMS has estimated will be needed to fund the average ACO in its start up and initial operations phases, unless waiver protection extends significantly beyond the three-year agreement period.

Failure to extend waiver protection as proposed by the AMA will probably discourage most, if not all, independent physicians from seriously considering joining with other physicians and other health care providers to create an ACO that could apply for approval in the shared savings

program. If the federal government does not want to limit the ACO Program to incumbent integrated delivery systems, then the OIG and CMS must be prepared to make the waivers available to the activities outlined in the comments that physicians and their potential ACO collaborators undertake in good faith.

Additional Recommendations

As referenced above, we urge the government to expand the above waivers to other financial arrangements necessary for and directly related to the operations of ACOs. To have practical consequence as well as to be effective, the waivers must apply to distributions of the underlying diagnosis related group (DRG), Medicare fee-for-service and other fee-for-service (FFS) payments that ACO providers will be receiving. It is far too restrictive to apply the waivers to distributions of the shared savings alone. For example, primary care physicians, specialists, or experienced clinical leadership may have to be recruited or otherwise incentivized to participate in the ACO. Other types of compensation arrangements will have to be created that will necessarily need to include, but not be limited to, innovative medical directorship agreements and participation agreements that utilize incentive-based compensation tied to quality or cost measures.

Although the Stark law exceptions that shield certain percentage- and unit-based compensation arrangements that would be extended to waive AKS liability in the proposed rule may adequately cover some of these particular financial arrangements, there will likely be considerable uncertainty regarding the extent to which existing Stark exceptions can accommodate these types of cutting-edge compensation arrangements. And, even in those circumstances where an exception from a *provider's perspective* might arguably apply, attempting to adhere to an exception is likely to create considerable uncertainty and impose significant costs to the extent the exception requires a fair market value evaluation. Obtaining an evaluation is often expensive (especially multiple evaluations), takes time, could be of limited utility in the context of innovative incentive-based compensation arrangements given that the fair market value evaluation of such arrangements may in large part be speculative, and not provide the perceived protection that evaluations of more conventional arrangements are often thought to provide. Accordingly, waivers should not be limited to distribution of shared savings, but extend to any compensation arrangement that is necessary to form an ACO.

In the same vein, we strongly urge the government to finalize the proposed rule to extend waiver protection to the distribution of shared savings from private payors to the ACO. Establishing an ACO solely for the Medicare population would unduly inhibit the creation of ACOs by limiting the economies of scale that a cross-section of patients and payors provide and present significant governance and management complexities that may pose competing and irreconcilable obligations.

CMS and the OIG have sought comments on whether additional waivers are needed to address the two-sided risk options laid out in the CMS proposed rule covering ACOs generally. We have

already expressed our extensive concerns with both options contained in the proposed rule and incorporate those comments here.

In addition, waiving the CMP law prohibiting inappropriate inducements provided to Medicare beneficiaries is essential to establishing a viable ACO. ACOs are likely to provide services that Medicare beneficiaries do not receive now—care management, extended office hours, online and telephone consultations are a few examples. It is important to waive CMP so these extra services are not viewed as inappropriate (illegal) inducements.

While we are generally supportive of the decision to propose ACO related waivers, we urge the Secretary to issue **separate waivers that are broader under the authority granted by Section 1115A** of the Social Security Act, enacted under the ACA through the Center for Medicare and Medicaid Innovation.

State Fraud and Abuse Laws

We are concerned that the proposed rule does not address the impact or options available to waive state fraud and abuse laws. This could present a significant barrier to participation in the ACO, particularly for those physicians and organizations that serve beneficiaries who are dually eligible for Medicare and Medicaid. As a result of the ACA, states have received a significant new investment in program integrity funding and many have either already adopted or in the process of adopting new laws that parallel federal program integrity laws. At least 37 states have enacted an anti-kickback statute and at least 34 states have enacted a statute prohibiting self-referral. Some of the state laws mirror the federal AKS and Stark law, while others differ considerably. In addition, some of the state laws apply only to state health programs, such as Medicaid, while others apply to any referral of health care services.

The following is simply one example of the complexity of navigating the state and federal program integrity laws. The purpose of which is to police financial arrangement based on a different payment model—fee for service—with also different expectations about integration.

New Jersey has a state anti-kickback and self-referral law. New Jersey's anti-kickback law which applies to the Medicaid program prohibits any provider, person, firm, partnership, corporation, or entity from soliciting, offering, or receiving any kickback, rebate or bribe in connection with furnishing items or services paid by the Medicaid program or receiving any benefit or payment by the Medicaid program. Any person who violates this law would be guilty of a crime of the third degree and liable for a penalty of not less than \$15,000 and not more than \$25,000 for each violation.

New Jersey's self-referral law applies to health care practitioners and prohibits practitioners from referring a patient or directing an employee to refer a patient to a health care service in which the practitioner, or the practitioner's immediate family has a significant beneficial interest. This provision is subject to some exceptions, but even if the referral is permitted, the practitioner must disclose the financial interest to the patient in a written disclosure form as prescribed by the State

Donald Berwick, MD

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Board of Medical Examiners. The disclosure form must also be posted in a conspicuous place in the office. We urge CMS and the OIG, to the maximum extent practicable, to preempt parallel state laws or set-up a means of assisting providers to work with states to address these barriers.

ANTITRUST

We urge CMS to consider the attached letter to the Federal Trade Commission (FTC) and the Department of Justice (DOJ) concerning the proposed Statement of Antitrust Enforcement Policy regarding ACOs alongside our comments on the proposed ACO Program. We recommend significant modifications to both proposals given that, if not properly developed, the ACO requirements and antitrust clearance process could have a significant and negative impact on the ability of physicians, hospitals, and other eligible ACO entities to successfully form and participate in ACO models.

PRIVATE INUREMENT

The AMA urges CMS to ensure that tax-exempt ACOs are permitted to distribute the ACO's shared savings with physicians and other providers or stakeholders who participate in the ACO. This should be permitted without risk of losing the ACO's tax-exempt status.

The AMA thanks CMS for this opportunity to provide our views on this potentially ground-breaking ACO program. We look forward to working with CMS, the OIG, FTC and the DOJ as we move forward in developing ACOs and many other delivery and payment models that can form the basis for a new Medicare physician payment program that increases value and improves quality for patients.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mike Maves".

Michael D. Maves, MD, MBA