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June 6, 2011

Donald Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1345-P
P.O. Box 8013
Baltimore, MD 21244-8013

Subject: Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; CMS-1345-P

Dear Administrator Berwick,

On behalf of our 4,000 neurosurgeon members, the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) appreciate the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with feedback on its proposed regulation regarding the Medicare Shared Savings and Accountable Care Organization (ACO) Program, authorized under Section 3022 of the Affordable Care Act. While the AANS and CNS support efforts to promote high quality and efficient care, we believe that the ACO proposal, as currently written, is overly prescriptive, operationally burdensome, and includes incentives that are too difficult to achieve to make the program attractive. We encourage CMS to test multiple new payment and care delivery models and to ensure that each takes into consideration the diversity of patients and physician practices; preserves patient access to specialists and necessary medical therapies; and does not stifle medical innovation. Listed below are organized neurosurgery's comments on specific aspects of the proposed Shared Savings and ACO Program.

Executive Summary

The AANS and CNS support efforts to experiment with innovative models of healthcare delivery and payment reform. However, we question the ability of the shared savings model to bring value to a system that is currently plagued by more fundamental problems, such as a flawed sustainable growth rate formula, undervalued services, a broken liability system, and disincentives to make long-term investments in care improvements. The shared savings model, as currently proposed, also offers specialists very few incentives to participate given restrictions on leadership and a high degree of risk offset by very few benefits. Given these concerns, we encourage CMS to go back to the drawing board and test a range of payment and delivery models that target more essential reforms and benefit a wider range of stakeholders, including specialists.

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In terms of specific aspects of the ACO proposal, the AANS and CNS make the following recommendations:

- The ACO governance structure should rely heavily on physician leadership, clinical expertise, and evidence-based medical practice. It is especially critical that specialists, who are otherwise limited in their ability to form and lead an ACO, have adequate representation on the governing body.
- The AANS and CNS oppose retrospective assignment of patients to an ACO since it will create uncertainty and confusion and discourage physician participation in the model.
- Shared savings programs must not stymie innovation or restrict patient access to the most appropriate care, regardless of the cost. Not requiring specialists to be exclusive to one particular ACO is a key element of preserving patient access and choice.
- Care coordination requires the provision of meaningful feedback on a regular basis.
- While transparent processes are critical, CMS should only publicly report information that will benefit patients and inform consumer decision-making. Public reporting of the specific dollar amounts of shared savings and losses is not necessarily useful information.
- The AANS and CNS oppose the two-sided risk model under which ACOs would have to repay a share of any losses experienced by Medicare. The high initial investment necessary to establish an ACO, paired with the need to achieve cost savings and bear the risk of potential loses will pose many challenges for ACOs and will inhibit participation in the model. The two-sided risk model also fails to recognize that improvements in quality and efficiency often require increased investments in modified processes.
- The proposed list of quality measures is excessive and overly burdensome, the all-or-nothing approach to reporting is impractical, and the performance threshold targets are overly aggressive. CMS should offer ACOs greater flexibility in selecting appropriate measures and mechanisms for reporting those measures.
- We encourage CMS to adopt risk adjust mechanisms that are relevant to the ACO model and that appropriately account for differences in patient populations. Risk adjustment should occur continually under the ACO program so that is always based on the ACO's current patient population, and should apply to both expenditure benchmarks and quality measurements.
- The meaningful use requirements are too ambitious given a lack of experience with meaningful use criteria and an infrastructure that does not yet fully support interoperable data exchange.
- The ACO model should recognize the role of patients in improving health and keeping costs down.
- The ACO proposed rule is silent on the issue of professional liability and we are concerned that providers participating in ACOs face a potential increased threat of litigation. The federal government should therefore provide physicians who are complying with ACO guidelines with reasonable medical liability protections.

General Comments on the Shared Savings Model

The basic concept of "shared savings" appears promising on the surface. If a healthcare system or provider reduces total spending for its patients below a level predetermined by a payer, the provider is rewarded with a portion of the savings. The assumption is that the payer would still spend less than it would have otherwise, and that the provider would earn more revenue than otherwise expected. However, there are some fundamental flaws to this approach that make it far less desirable as a payment reform than it might first appear.

For one, the shared savings model does not truly fix the underlying problems of the current Medicare payment system. Key services that are not paid for today still would not be paid for under the ACO model and services where fees are already too low to cover costs would continue to lose money. Furthermore, ACOs and other shared savings models do nothing to address the problems associated with the flawed Sustainable Growth Rate (SGR) formula, which is currently used to determine physician payment updates. Without fixing the SGR, physicians will receive less reimbursement for the exact same procedure each year, regardless of increases in cost, inflation and expenses. Being at constant risk for these cuts greatly inhibits a physician's ability to adapt to new care delivery models and, as numerous recent surveys have demonstrated, may ultimately affect patient access to care.

Similarly, we question the shared savings model's value as a sustainable approach to payment reform. What happens after the initial savings have been achieved and shared? Even if costs remain lower than expected over time, the underlying payment system will remain the same. As a result, providers will be deterred from making significant long-term investments in care improvements. Creating an incentive for providers to improve quality and rein in unnecessary spending is a good idea, but only if it is coupled with critical reforms to the underlying payment system.

The shared savings model also exposes providers to increased risk without providing them with additional resources. It assumes that there is no cost to the provider for making systematic changes to improve quality and provide care more efficiently. Most of the programs throughout the country that have demonstrated reduced hospitalizations, for example, have required an increase in upfront spending. Under the shared savings model, the provider has no assurance that increased costs will be covered, and under CMS's proposal for ACOs specifically, providers would actually be penalized for incurring higher costs. Furthermore, in order for any savings to be realized under this model, some provider will get less revenue than he/she would have otherwise received. If that provider is participating in the effort to reduce spending, returning an arbitrary share of the savings reduces the amount they lose, but they will likely still get less revenue than their actual cost of delivering services, which will discourage them from participating in efforts to create the savings in the first place.

Finally, the shared savings model may not be the best fit for specialists. The proposed ACO program, in particular, offers procedure-oriented specialists very few incentives to participate. It is clear that CMS anticipates that primary care physicians will play a key role in controlling both the quality and cost of services provided to the Medicare beneficiaries assigned to an ACO, functioning as "gatekeepers" in determining access to specialty care and testing. While specialists may risk losing patient referrals if they do not join an ACO, they will inevitably weigh this risk against the risk of being held accountable for care outside of their control and the extra responsibilities that come with joining an ACO. These include burdensome reporting requirements for quality measures that have little relevance to specialty medicine and investment in "meaningful use" of health information technology (HIT) that requires adherence to criteria developed for primary care. Furthermore, in those areas where there is more than one ACO, specialists may be required to institute different patient care protocols and comply with different and sometimes conflicting administrative requirements for each ACO with which he or she participates.

Given these limitations, we encourage CMS to test, through the new Center for Medicare and Medicaid Innovation, various payment and care delivery models that target a range of stakeholders. One example is allowing payers and providers to share risk for high return-on-investment value improvement programs. Modeling off of an approach used in the banking and investment industry, a provider would present a business plan for generating a return on investment for a payer and the payer would commit a portion of the expected savings as an upfront payment to enable the provider to carry out the plan. The provider would accept accountability for achieving the expected savings and

share in the risk if the savings did not materialize. This would give providers more flexibility in choosing which reforms work best for them. Bundled payments are another example. Under this model, payments are linked to a particular procedure or episode of care and may offer specialists more of a direct incentive than the shared savings model to work with hospitals and others to bring down the cost of care. The AANS and CNS do not necessarily endorse any one of these models over another, but instead encourage CMS to work with other payers to test various options that target the differing needs of each healthcare stakeholder.

ACO Governance

We are pleased that CMS proposes a governance structure for ACOs that relies heavily on physician leadership, clinical expertise, and evidence-based medical practice. We support the provision that a board-certified physician, licensed in the state in which an ACO operates, serve as medical director of the ACO and have clinical management and oversight; that the governing body also include a physician-directed quality assurance and process improvement committee; and that the governing body work to develop and implement evidence-based best practices. Since specialists are limited in their ability to form and lead an ACO, it is critical that they at least have adequate representation on the governing body.

Beneficiary Assignments

ACOs must have a minimum of 5,000 Medicare beneficiaries assigned to primary care physicians. CMS will use retrospective assignment of patients after a performance period of one year to determine who received care from an ACO. Beneficiaries will be assigned to an ACO based on primary care services rendered by those physicians. Primary care physicians for whom beneficiary assignment is made must be exclusive to one ACO for a three-year period. Providers for which assignment is not dependent on (e.g., specialists, hospitals) can participate in more than one ACO.

The AANS and CNS have serious concerns about retrospective assignment of patients to an ACO. Under retrospective assignment, neither the patient nor the physician knows that CMS is assigning accountability to the physician for the costs of all a patient's care until after the care has already been delivered. This uncertainty will make it difficult to attract ACOs and will increase the complexity of determining which risk model to select (see payment and risk models discussion below).

Ensuring Patient Access to Needed Care

CMS proposes "strong protections" to ensure patients do not have their care choices limited by an ACO. ACOs would be prohibited from using managed care techniques, such as limiting the beneficiary to certain providers, utilization management, or requiring prior authorization for services for Medicare beneficiaries. ACOs also cannot adopt policies that prohibit patients from seeking care outside of the ACO. CMS has proposed a vigorous monitoring plan that includes analyzing claims and specific financial and quality data. It plans to generate quarterly and annual aggregated reports, visit some ACOs on site, and perform beneficiary surveys to make sure that ACOs are not stinting on care and are not avoiding at-risk patients.

We cannot overemphasize the importance of these protections. Shared savings programs could very easily stymie innovation and restrict patient access to care by denying needed referrals to specialists and to newer, higher cost tests and interventions even when it is the most appropriate treatment for the individual patient. CMS's proposal to not require specialists to be exclusive to one particular ACO is a key element of preserving patient access to care and choice of provider. Limiting specialists to

one ACO, especially in areas of the country where there are shortages of particular specialists, could encourage the formation of ACOs with undue market power and ultimately impose restrictions on Medicare beneficiary access to care. This provision is especially important for small and critical specialties such as neurosurgery, which has less than 4,000 practicing members spread across the U.S. The AANS and CNS strongly support this aspect of the rule and urge CMS to ensure that patients are not limited to certain providers and can maintain the freedom to choose providers that best fit their needs each time care is sought.

It is equally critical that patients continue to have access to treatments that are the most appropriate for their individual needs, even if those treatments require higher spending. As such, shared savings programs should continue to encourage advances in medical treatments and technologies. The long-term benefits of medical progress far exceed the short term costs. We encourage CMS to require ACOs to demonstrate how it is ensuring patient access to specialty care, how it is preserving patient and physician clinical decision-making, and how it is informing patients of their full range of treatment options—including possible new and emerging technologies or treatments that may only be available outside an ACO.

Provision of Data

CMS proposes to prospectively provide ACOs, by request, with aggregated data reports for potentially assigned patients. CMS would provide certain identifiable claims data, including Parts A, B and D, on a monthly basis in a standardized format to assist in care coordination efforts.

The AANS and CNS agree with CMS that an important barrier to improving care coordination is lack of information, and we see great value in providing ACOs with continuous data so that they can better manage patient care. However, we question the value and relevance of reports that do not even necessarily reflect the ACO's retrospectively assigned patient population. We also question the role of claims data, in general, in helping providers to identify cost savings. Claims data may reveal that a test was ordered and repeated on a patient, but it would not provide clinically meaningful information such as the test results or the reasons why it was reordered (e.g., perhaps the ordering physician did not have access to the initial results). We also question whether CMS has the resources to fulfill the obligation of providing ACOs with meaningful and timely feedback and whether the information provided to ACOs will be sufficient for managing patient care and financial risk. Given the influx of federally mandated quality improvement initiatives and payment reform demonstration projects under CMS's authority, the agency has recently admitted that it is over-tasked and under-resourced to provide physicians with meaningful feedback on a regular basis. This has been a particularly prominent issue in regards to feedback under the PQRS and e-Prescribing Incentive Program.

Public Reporting and Transparency

The proposed rule would require ACOs to publicly report certain information, including ACO participants, ACO representatives to its governing body, shared savings performance payments received or shared losses payable to CMS, the total portion of savings invested in infrastructure (including portions distributed among ACO participants), and quality performance standard scores.

While we support transparent processes, public reporting of the specific dollar amounts of shared savings and losses is not necessarily information that will benefit patients or inform consumer decision-making. In fact, it may actually further confuse patients, many of whom are currently grappling with the flood of complicated healthcare data already available in the public domain. In addition, claims and spending data provide insufficient clinically relevant information to draw

conclusions about physician quality or efficiency. For example, an ACO may incur increased costs due to caring for a higher risk patient population that other providers may not have felt comfortable caring for. The inability of this ACO to meet the spending targets would not necessarily indicate inappropriate care or wasteful spending. However, public reports based on claims data would not get this message across. As a result, public reporting may discourage ACOs from treating sicker, more complicated, or socioeconomically disadvantaged patients and could create a serious access problem for those who need care the most.

We also believe that it is much too early to consider public reporting of quality performance scores given the excessively high reporting burden (see additional concerns below) and the fact that many of the quality measures have not even been tested yet and do not have proven links to improved outcomes. Until CMS gains more experience with the ACO Program and other programs that use these measures, it should not release performance information to the public.

Payment and Risk Structure

CMS is proposing that hospitals and physicians participating in an ACO continue to be paid according to the same Medicare Part A and B payment schedules as are currently used. ACOs that obtain savings for Medicare by achieving total Medicare claims submissions below a pre-calculated benchmark may share in the savings. The benchmarks will be updated each year by the total per capita increase in Medicare spending nationally.

CMS proposes that payments to ACOs follow one of two tracks:

- **Track 1 (the one-sided model)**: ACOs will only face upside risks during their first two years, during which it will receive a share of savings below a designated benchmark. During year three, however, it will have to repay a share of any losses Medicare experiences compared to the benchmark. Under this structure, the percent of shared savings/losses is limited and not as high as under Track 2.

- **Track 2 (the two-sided model)**: Under this track, ACOs will face two-sided risks for the entire three years of the program (i.e., sharing in a portion of savings and repaying a portion of losses). ACOs will receive a higher share of any savings generated by the ACO, but are also responsible for paying back a larger share of any losses incurred. This track will likely be more attractive to more well-established groups who have experience providing care through a coordinated network.

A minimum savings threshold will be established for each ACO before any savings can be returned to the ACO. For ACOs in Track 2, the minimum savings rate is 2%, but for smaller ACO organizations in Track 1 it may be higher due to concern that their savings may result from random variation in spending rates instead of performance. Once the threshold is exceeded, CMS sets maximum sharing rates for both savings and losses, which take into account not only savings and losses to Medicare, but also the ACOs performance on quality metrics and other factors. CMS also sets caps for maximum shared savings and losses.

The proposed rule also outlines some provisions intended to ensure that ACOs will be able to repay any shared losses for which they are ultimately held accountable. These include initially withholding 25% of shared savings and providing CMS the ability to tap into line of credit.

The AANS and CNS believe that achieving the cost savings anticipated by the proposed rule will pose many challenges for ACOs. With CMS estimating the start-up cost of an ACO to be $1.8 million, and more recent estimates by the American Hospital Association as high as $26.1 million, physicians will have to invest a significant amount of resources to participate in an ACO, which will make cost savings more difficult to achieve. Another challenge to achieving cost savings is the fact that Medicare beneficiaries assigned to ACOs are not precluded from obtaining care from non-ACO providers. As a result, spending and care patterns outside of a physician's control may still be attributed to his/her ACO. Given the high start-up costs of becoming an ACO, we also are concerned about CMS's proposal to set a higher minimum savings threshold before any savings can be returned to an ACO under Track 1 since ACOs following this track will likely be smaller and in more acute need of the returned savings to cover its initial investment. Similarly, withholding shared savings upfront to protect against potential future losses will make it even more challenging for an ACO to recoup start up costs and further disincentivizes participation in the program. Most importantly, the program fails to take into account the fact that certain improvements in care may actually cost *more* and require investments in modified processes and infrastructure, such as health information technology and additional staff to coordinate quality data collection.

The short term nature of the savings calculation and the quality reporting period is also problematic since it discourages *longer term* patient management, preventive care and clinical outcomes data collection. Long term projects, such as smoking cessation, may only reap benefits in later years and may therefore be of little value to an ACO. In fact, such interventions may actually hurt an ACO by driving up short term costs.

Finally, the AANS and CNS strongly oppose CMS's proposal to require ACOs to repay a portion of Medicare spending that exceeds an expected cost threshold. This requirement, in addition to the high initial investment necessary to establish an ACO, will further inhibit ACO participation. The Affordable Care Act only discusses instances where ACOs would share in the savings achieved for Medicare. The proposal to hold ACO's accountable for losses is punitive, creates a major disincentive to participate in the program, and contradicts the intent of the law.

Quality Measures

CMS proposes 65 measures to calculate ACO quality performance across 5 key domains, including patient experience. Less than half (30) are measures that have already been used in the Physician Quality Reporting System (PQRS), while 28 are new (either endorsed by the National Quality Forum or adopted by CMS). One measure also incorporates 9 hospital acquired conditions (HAC).

In the first year, ACOs would only have to report on quality measures, but in the remaining two years, ACOs would have to meet quality performance standards. CMS proposes that ACOs report measures either through claims or patient surveys.

CMS proposes a "performance score approach" to determine the percentage of shared savings that an ACO receives following year one. Under this approach, CMS will set benchmarks for each measure using claims data. An ACO will receive between 0 to 2 points for each quality measure, depending on its performance. If an ACO receives a 90% or better score on a measure, it will receive 2 points for that measure; if an ACO receives less than 90%, it will receive fewer points, down to 0 for an ACO that receives less than 30% for a quality measure. ACOs would have to meet minimum thresholds for ALL measures in order to be eligible for shared savings, regardless of how much costs were reduced.

The AANS and CNS believe that the breadth of measures proposed for this program is overly burdensome and impractical. With such a large number of measures, it will be extremely difficult for physicians to meet the reporting requirements, let alone the subsequent performance thresholds. We highly encourage CMS to lower the number of measures that must be reported under the program. We also oppose CMS's proposed all-or-nothing approach to meeting the reporting requirements (i.e., 100% compliance). This requirement is excessive considering the number of measures proposed. While we understand CMS's intent to avoid a situation where costs are being targeted at the expense of quality patient care, the requirement to meet performance thresholds on all measures is overly aggressive, especially since not all of the measures have been tested or have proven links to improved patient outcomes. The compliance requirement should either be lowered or phased in over the long-run as ACOs gain experience in this area.

We also urge CMS to offer ACOs greater flexibility in selecting appropriate measures. As we have noted in previous comments, adopting a one-size-fits-all approach to quality measurement will do very little to improve the quality of patient care and may actually have the opposite effect. By so tightly specifying measures and imposing irrelevant and clinically inappropriate reporting requirements on physicians, limited time and valuable resources will be diverted from more meaningful efforts to improve patient care. ACOs should be permitted to report on a hybrid of national and local measures that are most relevant to their unique practice and patient population. To the extent possible, and in a manner that preserves flexibility, CMS should also coordinate ACO reporting requirements with that of other federal programs, such as the Physician Quality Reporting System (PQRS) and Electronic Health Record (EHR) Incentive Program. ACOs that meet the ACO quality performance measures should be automatically eligible for the PQRS incentive payment and vice versa in order to minimize physician reporting burden, duplication of effort, and confusion.

The AANS and CNS also have concerns about the specific measures proposed by CMS. As seems to be the case with many federal quality reporting programs, there are no measures related to surgery and very few that are relevant to non-primary care specialists. There also are a number of proposed quality measures that are linked to hospital reporting (e.g. admissions, readmissions, and HACs). As a result, ACOs would need the primary hospital(s) to which the assigned Medicare population is referred to participate in the ACO. This also raises questions about how ACOs that are not affiliated with a hospital-- an arrangement permitted under the proposed rule-- would qualify for these measures. We also urge CMS to reconsider its proposed HAC composite measure. Individually, the HAC measures ignore the challenges inherent to defining "preventability" in healthcare, do not include a mechanism to adjust for patient case-mix or flag a case where a complication occurred despite strict adherence to best practices, potentially expose providers to increased medical liability risks, and have no proven links to improved patient quality. The weaknesses of these measures will be even more pronounced in the form of a composite.

The AANS and CNS also request that CMS reconsider the proposed "performance score approach" since it uses arbitrary percentiles to define varying levels of performance. For example, there is little difference between a performance score of 89% and 90%, yet under the "performance score approach," an ACO with an 89% score would receive fewer points which could translate into significantly fewer shared savings. We encourage CMS to instead consider a "minimum threshold" approach under which an ACO would receive all potential savings as long as it met minimum quality standards. Furthermore, while we appreciate the transitional step of requiring only reporting of measures in Year 1, we urge CMS to extend this requirement beyond year 1. The PQRS has demonstrated that many years are needed to work out the kinks in quality reporting programs. ACOs should be given the opportunity to gain experience with these new quality reporting requirements and

to work with CMS to identify and correct problems before CMS transitions to evaluations based on performance.

Finally, we encourage CMS to allow ACOs to report quality measures via both registries and EHRs since many providers are already using these tools to meet other quality improvement objectives.

Risk Adjustment

In calculating expenditure benchmarks, CMS aims to "make appropriate adjustments to reflect the health status of assigned patients as well as changes in the ACO's organizational structure that would affect the case mix of assigned patients rather than apparent changes arising from the manner in which ACO providers/suppliers code diagnosis." CMS proposes to use a prospective risk adjustment model used under the Medicare Advantage (MA) program. The MA CMS-HCC model covers patient demographic factors (e.g., sex, age, basis for Medicare entitlement and Medicaid status), as well as diagnostic information to create a risk score for each beneficiary. Using this methodology, CMS proposes to create a single risk adjusted score for the ACO's historically assigned patient population, which will then be applied throughout the three-year period to the annual per capita expenditures for patients attributed to the ACO. Changes in the risk score for patients attributed to the ACO over the three-year period will not be incorporated.

We appreciate CMS's effort to risk adjust for patient differences. However, the effect that the MA CMS-HCC risk adjustment model will have on the financial viability of ACOs remains unclear. Under the MA program, MA plans receive a monthly capitation rate for each patient. The CMS–HCC risk adjustment model is then used to decrease this rate for lower-cost patients and to increase it for higher-cost patients, reducing the incentive for plans to risk select only the healthiest patients and not penalizing plans that provide care for the most seriously ill patients. Unlike MA plans, ACOs will not be directly compensated for higher cost patients and will need to find ways to care for these patients without the same financial assistance provided to MA plans.

Since risk adjustment is such a fundamentally critical component of any program that measures the quality and cost of providing healthcare, we believe that risk adjustment should be calculated continually under the ACO program (i.e., not just once over the three years) and should always be based on the ACO's current patient population. If not, ACOs will receive no credit and/or a potential penalty for treating more complex or otherwise riskier patients, which will serve as an inherent incentive for ACOs to avoid those patients that need care the most.

CMS only proposes a risk-adjustment mechanism for calculating ACO expenditure benchmarks. However, it is unclear to what extent CMS will apply risk-adjustments when calculating ACO performance on specific quality measures. We highly encourage CMS to incorporate risk-adjustment mechanisms to the greatest extent possible so that determinations regarding ACO quality and spending are fair and accurate and so that riskier populations are not denied care.

Health Information Technology

CMS proposes that by year 2, at least 50% of an ACO's primary care physicians must be meaningful EHR users. We suspect this will be difficult to achieve since we do not yet know how stage 1 of the meaningful use program is working or how many physicians will have adopted EHRs by the time the ACO program starts. Collaboration and coordination of patient care requires adoption of an infrastructure that enables collection and evaluation of data and feedback across multiple stakeholders. Without interoperable HIT systems in place nationwide, it will be difficult for ACOs to

form and to meet CMS's goals for the program. We encourage CMS to first focus on establishing a proper infrastructure for data exchange so that the shared savings model has more of a chance to succeed.

Patient Responsibility

The ACO model, as currently proposed, focuses on incentivizing the health care provider to promote wellness and cost-effective behaviors. However, the AANS and CNS question CMS's strategy to leverage the success of ACOs on physician accountability alone. When a patient makes independent choices shown to reduce life expectancy and increase health care costs, should he or she not be held accountable, as well? CMS's current proposal fails to recognize the role of patients in improving health and keeping costs down. The healthcare provider plays an undeniably critical role in facilitating good patient outcomes and ensuring appropriate and efficient care. However, poor outcomes can, in part, be the result of a patient's failure to engage in healthy behaviors, and overutilization can, in part, be driven by patient demand. The AANS and CNS believe that the shared savings model should promote, to some extent, patient responsibility and accountability for health, utilization of services, and spending. True quality improvement and cost savings can only be realized when consumers are empowered with responsibility over their own medical care.

CMS should consider ways to incorporate patient responsibility into the Medicare shared savings program or, at the very least, develop a mechanism through which ACOs can devote a portion of spending to incentivizing healthy patient behaviors that would not count toward the ACO's expenditure benchmark. Various private sector employers and state Medicaid programs offer patients incentives to engage in healthy behaviors-- such as regular checkups, smoking cessation programs, weight loss, and medication maintenance. Evidence shows that these rewards are powerful motivators and that they ultimately improve health and result in lower health care spending over the long-term. Similarly, we recommend that CMS incorporate patient compliance measures into the severity adjustment methodology called for under the ACO proposal. Adjusting for patient compliance when calculating expenditure benchmarks will help to more accurately reflect the case mix of patients assigned to an ACO.

Finally, the AANS and CNS question the logic of not informing a patient of his or her ACO assignment. While we support preserving patient choice of provider, patients are more likely to engage in healthy protocols if they know that they are linked to a particular provider and that non-adherence to healthy behaviors puts their preferred physician or system at risk for maintaining a long term presence in the community. We also strongly believe that ACOs should not be allowed to refuse a patient, but at the same time, should be permitted to exclude from the case mix used to measure quality and calculate cost savings those patients who are seriously non-compliant.

Malpractice Safe Harbors

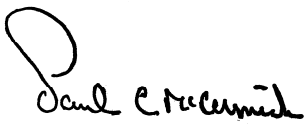
The ACO proposed rule is silent on the issue of professional liability and we are concerned that providers participating in ACOs face a potential increased threat of litigation. Physicians participating in an ACO will be subject to various quality and cost effectiveness metrics as outlined in the proposed rule. We can envision any number of scenarios where physicians complying with these requirements could be subject to malpractice claims. One example is the situation where the ACO adopts appropriateness criteria for utilizing diagnostic imaging. A physician following these imaging guidelines might refrain from ordering an MRI for a patient complaining of headaches, only to later discover that the patient has a brain tumor. The patient could conceivably bring a malpractice suit against the treating physician for a failure to diagnose the brain tumor – and quite possibly prevail –

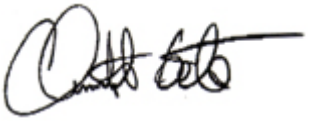
despite the fact that the physician followed the ACO's evidence based quality/efficiency guidelines. This presents the treating physician with a dilemma – follow the ACO policies to meet CMS's financial and quality requirements or order the test on the off-chance that there might be a serious, life threatening cause of the patient's headaches.

Given this catch-22, it seems appropriate for the federal government to provide physicians who are complying with ACO guidelines with reasonable medical liability protections. One approach would be to deem an ACO and/or ACO-participating physician to be an employee of the Public Health Service for purposes of any civil action that may arise due to providing ACO-related services. This would require patients alleging malpractice to pursue their claim under the Federal Tort Claims Act. Another approach would be to allow physicians to introduce the relevant ACO guidelines into evidence as an affirmative defense to any medical liability claim. In addition to an affirmative defense, the standard of proof in any medical liability lawsuit in which a physician utilized ACO guidelines should be clear and convincing evidence.

The AANS and CNS appreciate the opportunity to provide CMS with feedback on the Medicare Shared Savings and ACO Program. Should you have any questions, please feel free to contact us.

Sincerely,





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