



**AMERICAN ACADEMY OF
OTOLARYNGOLOGY—
HEAD AND NECK SURGERY**

June 6, 2011

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 Academy of Otolaryngology- Head and Neck Surgery (Academy) is submitting comments on the *Medicare Shared Savings Program: Accountable Care Organizations* (ACO Program) Proposed Rule. The Academy is the world's largest organization representing specialists who treat the ear, nose, throat, and related structures of the head and neck. The Academy represents more than 12,000 otolaryngologist—head and neck surgeons who diagnose and treat disorders of those areas.

The Academy is supportive of the Centers for Medicare & Medicaid Services' (CMS) stated goals of the Shared Savings Program, namely to provide better care to Medicare patients, to provide better health to populations, and to decrease the cost of health care by reducing waste in the system. We are also generally supportive of the concept of a properly implemented accountable care organization (ACO) as a mechanism to improve quality, delivery, and coordination of patient-centered care for surgical patients. However, we have concerns that the ACO concept, as currently proposed, will be extremely difficult to implement. We also believe that the proposed rule does not adequately acknowledge and account for the importance of specialists, specifically otolaryngologists, in the implementation of ACOs. The success of an ACO depends not only on the participation of qualified primary care physicians, but also on specialists, who will be crucial to the improvement of quality of care. Additionally, lack of coordination between primary care physicians and specialists can result in duplication of efforts (for example, lab tests) and poor support for preventing complications, thereby reducing potential shared savings. As such, for an ACO to be successful, it will be necessary to promote coordination with specialists, even specialists who are not ACO participants.

The Academy appreciates the opportunity to provide input on these important regulations and highlights the following recommendations:

- ***CMS needs a mechanism to measure whether patients in an ACO are not restricted by physician influence to seek care outside the ACO and that patients are receiving necessary care in a timely manner.***

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- *Until interoperability capabilities are developed and are in widespread use, ACOs should not be mandated to have a plan in place to electronically exchange summary of care information when patients transition from one provide/setting to another within and outside of the ACO, unless facsimile or scanned documents meets this requirement.*
- *The Academy recommends that ACOs be able to meet the beneficiary experience of care survey requirement through the utilization of Surgical CAHPS.*
- *The ACA does not require public reporting of ACO performance information, and we urge CMS to not publicly report the information.*
- *The Academy supports CMS' proposal to allow specialists the ability to participate in more than one particular ACO.*
- *The Academy is in support of the AMA comments regarding the payment and risk aspects of the Shared Savings Program. We recommend that CMS provide a payment option that includes shared savings only ("onesided risk") without the mandatory shared loss provision and that there should be an option allowing ACOs to receive shared savings, without the down-side risk. In addition to appropriate risk adjustment methodologies, CMS should establish limits on an ACO's accountability for the total cost of services to any individual patient. CMS should also provide timely and detailed feedback to physician practices to enable them to identify opportunities to make improvements in cost and quality and to successfully implement them.*
- *The Academy is disappointed to see that there are no surgical measures proposed or measures specific to otolaryngology. The exclusion of such specialty-specific measures will hinder participation by otolaryngologists in ACOs or impact ACOs inclusion of otolaryngology in the ACO.*
- *The Academy 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.*
- *CMS' proposed quality reporting mechanism requirements are unrealistic and the Academy believes CMS should adopt Option 2, Quality Threshold based on our experience with PQRS.*
- *The Academy seeks clarification on the proposed PQRS group practice reporting option under the Shared Savings Program, specifically ACOs submitting data on behalf of the eligible professionals in an effort to qualify for the PQRS incentive as a group practice and not qualifying as individuals.*



II. B Eligibility and Governance

B. 9. Processes to Promote Evidence-Based Medicine, Patient Engagement, Reporting and Coordination of Care

CMS proposes that ACOs meet several criteria consistent with a requirement of the Patient Protection and Affordable Care Act (ACA), that the ACO have a leadership and management structure that includes clinical and administrative systems. One of these criteria is the requirement that the ACO develop and implement evidence-based medical practice or clinical guidelines and processes for delivering care. The Academy supports the use of evidence-based guidelines developed by appropriate medical specialty organizations and based on non-biased, well-designed, prospective, randomized studies. Evidence-based guidelines must also be shown to meaningfully improve care. We are concerned that some evidence-based guidelines are not developed with the necessary rigor and evidence and therefore may not lead to a meaningful improvement in care. Implementation of such evidence-based guidelines can vary dramatically and can consume substantial financial and staffing resources. If there is no evidence of an improvement in care, implementation of such evidence-based guidelines could potentially even cause harm.

The Academy has a well-developed, rigorous process for clinical practice guideline development. Since 2006, the Academy has formed multidisciplinary panels to address: Acute Otitis Externa (AOE), Otitis Media with Effusion (OME), Hoarseness, Benign Paroxysmal Positional Vertigo, Adult Sinusitis and Tonsillectomy. Through a joint partnership with AMA's Physician Consortium for Performance Improvement (PCPI), AOE and OME measures were developed utilizing the guideline as a basis for the work. Currently, there is another AMA PCPI/Academy panel working on the development of sinusitis measures from our Adult Sinusitis clinical practice guideline. We therefore support the inclusion of evidence-based guidelines that can be shown to meaningfully improve care.

Processes to Report on Quality and Cost Measures

Please reference Section E. Quality and Other Reporting Requirements for our comments regarding reporting of quality measures.

Processes to Promote Coordination of Care

Care coordination is fundamental to managing both episodes of care and chronic conditions across physician specialties and healthcare settings. The Academy is glad to see that CMS proposes "to prohibit the ACO from developing any policies that would restrict a beneficiary's freedom to seek care from providers and suppliers outside of the ACO". To ensure this, **CMS needs a mechanism to measure whether patients in an ACO are not restricted by physician influence to seek care outside the ACO and that patients are receiving necessary care in a timely manner.** In addition, the Academy is concerned that primary care providers may try to manage a patient's condition and not appropriately refer the patient to a



specialist because the potential higher cost of specialty care will potentially decrease the ACOs chance of meeting CMS benchmarks and achieving shared savings.

The Academy believes ACOs may feel it is not necessary to include otolaryngologists. Therefore, we urge CMS to ensure that the correct processes are put into place so that Medicare beneficiaries can receive appropriate and timely referral for specialty care.

B. 10. Patient-Centeredness Criteria

The Academy believes that it is necessary for ACOs to have a process in place to exchange information among providers within and outside the ACO to advance quality healthcare. The Academy is concerned with CMS' proposal to include percentages of physicians meeting Stage 1 Health Information Technology for Economic and Clinical Health (HITECH) Act Meaningful Use (MU) requirements. In addition, the Academy is concerned that requiring ACOs to electronically exchange information will force specialists to contract exclusively with one ACO since interoperability does not currently exist and adopt the EHR technology of the primary care provider or hospital system within the ACO. The current state of EHRs only allows providers to view patient information internally and not outside of their practice. Even practices or hospitals that have the same software, but are not part of the same system or hospital cannot exchange information among one another. For example, in the Philadelphia area the major university hospital systems all use the same EHR product, but they cannot exchange information across hospitals systems or with providers outside the hospital, even if they utilize the same software. **Until interoperability capabilities are developed and are in widespread use, ACOs should not be mandated to have a plan in place to electronically exchange summary of care information when patients transition from one provide/setting to another within and outside of the ACO, unless facsimile or scanned documents meets this requirement.** Furthermore, specialists such as otolaryngologists may not choose to purchase EHR software that is meaningful use certified because the Stage 1 requirements do not, at this time, include otolaryngology-specific quality measures and/or because they could be required to adopt objectives and quality measures that are not fully applicable to their practice.

The Academy supports the Meaningful Use program in general but is concerned that many of the measures in Meaningful Use are primary care focused and the lack of exclusions makes it difficult for specialists to comply. For example, eight of the 15 Stage 1 core measures and three of the 10 Stage 1 menu options do not include an exclusion category. Furthermore, many of the exclusions for measures under both the core and menu sets do not allow an exemption for specialists who do not routinely perform the activity described. In addition to the overwhelming task of implementation, we feel that specialists should not also have to report on those measures that are not relevant to their scope of practice or to the services that they routinely provide to their patients. We are concerned that specialists may be placed into an inclusive category that will automatically penalize them in a way that is patently unfair.

Purchasing and maintaining electronic health record systems is very expensive, particularly for small physician practices. While having such systems is *desirable*, there is no evidence that



they are *essential* for physician practices to successfully coordinate care and manage costs. Indeed, there are many examples where physician practices deliver high quality, affordable, coordinated care in the absence of EHR, and there is evidence showing that implementation of such systems can have negative impacts on the quality and cost of care, particularly during implementation phases. Consequently, making acquisition and implementation of such systems a condition for being designated an ACO is inappropriate. The Academy urges CMS to limit any requirements for the structure or internal systems of ACOs to areas where there is clear evidence that high-quality, affordable care cannot be provided without such structures or systems in place.

Beneficiary Experience of Care Survey

The Academy is supportive of CMS incorporating beneficiary experience of care surveys, but has concerns with the mandatory requirement of utilization of the Clinician and Group CAHPS survey and publicly reporting the data. The Clinician and Group CAHPS surveys do not accurately capture patient experiences for surgical specialties. Often when a patient interacts with a surgical specialty, such as otolaryngology it is for an acute episode and the Clinician and Group CAHPS does not represent that type of interaction appropriately. In 2010, the CAHPS Consortium adopted and trademarked the CAHPS Surgical Care Survey. This survey was developed by the ACS and the Surgical Quality Alliance (SQA) to assess patients' experiences with surgical care, and more specifically, to encompass the domains of care for the surgical patient that the CAHPS Clinician & Group survey lacks, including: informed consent, shared decision making, anesthesia care, and post-op follow-up. Like the CAHPS Clinician & Group survey, the CAHPS Surgical Care Survey focuses on aspects of surgical quality that are important to patients and for which patients are the best source of information. The Academy recommends that the CAHPS Surgical Care Survey measures be included as a patient/caregiver experience domain. **The Academy recommends that ACOs be able to meet the beneficiary experience of care survey requirement through the utilization of Surgical CAHPS.**

It is also important to recognize, however, that patient and caregiver experience measures such as CAHPS and Surgical CAHPS cannot be collected through existing data systems such as claims data and electronic health records. They require special surveys of consumers, and the lack of resources available to conduct these surveys has been a principal barrier, slowing their implementation particularly outside of the hospital setting. Consequently, CMS will need to consider the provision of financial support for the collection and reporting of consumer experience data.

Since CAHPS and Surgical CAHPS was developed to measure the care delivered by individual types of providers in a fee-for-service environment, additional survey questions will likely need to be developed to measure patient experience issues that will be particularly affected by ACOs. Until the relationship between patient satisfaction and other outcomes is better understood, data collected on patient satisfaction is best used by physicians and health care organizations to identify opportunities for responding to patient needs. Moreover, until the collection methods associated with patient experience information are uniform and validated, such information should not be used to assess ACO performance.



The ACA does not require public reporting of ACO performance information, and we urge CMS to not publicly report the information. If CMS insists on moving forward with publicly reporting the information, CMS must approach both the collection and any reporting of such information, including patient experience data, thoughtfully to avoid having unintentional adverse consequences for physicians. Furthermore, CMS must invest resources to update their internal systems so the information can be submitted in a safe, secure manner. ACOs must also have the opportunity to review their information prior to it being publicly reported and have the opportunity to correct errors.

II. C. Establishing the 3-year Agreement with the Secretary

C. 1. Options for Start Date of the Performance Year

CMS proposes to establish an application process with an annual application period during which a group of ACOs would be evaluated for eligibility to participate in the Shared Savings Program. We agree with CMS that in light of the looming start date for implementing the Shared Savings Program in the first year of the program, a January 1 start date may not allow for enough flexibility for all those interested in completing an ACO application. As a result, we support CMS' suggested alternative of staggering the start dates and adding an additional start date of July 1 for the first year of the program. CMS states that it envisions such an alternative only being available in the first year of the program, but we recommend that a July 1 start date be allowed for the first two years of the program. The requirements involved to create an ACO are extremely complex and the process of completing the application will require extensive analysis, planning, time, and resources. *Therefore, we believe that a July 1 start date for the first two years of the program will enable additional qualified ACOs to participate in the early stages of the Shared Savings Program.*

II. D. Assignment of Medicare Fee-for-Service Beneficiaries

D. 1. Operational Identification of an ACO

In the proposed rule, the assignment of Medicare beneficiaries is dependent upon primary care physicians (PCP). The PCP would be committed to the ACO for a three-year period and be exclusive to that ACO. In contrast, specialists and other entities upon which assignment of beneficiaries is not dependent can participate in more than one ACO, and thereby facilitate the creation of competing ACOs. We agree that competition in the marketplace and patient access to a variety of providers can promote quality of care. 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, which, in turn, could reduce or eliminate the benefits to Medicare beneficiaries of what should have been the positive influence of market competition. *Therefore, the Academy supports CMS' proposal to allow specialists the ability to participate in more than one particular ACO.*

D. 3. Prospective vs. Retrospective Beneficiary Assignment to Calculate Eligibility for Shared Savings



In the proposed rule, CMS states the two basic options to assign Medicare beneficiaries to an ACO in order to calculate shared savings: prospective versus retrospective. CMS proposes to assign Medicare beneficiaries to an ACO retrospectively (that is, at the end of each performance period). The agency further proposes to assign beneficiaries to an ACO if they received a plurality of their primary care services (based on an analysis of allowed charges, no units of service) from primary care physicians within that ACO.

CMS also proposes to provide aggregate data to the ACO for its assigned population of Medicare patients during the benchmark period with additional data elements. The agency prefers this option because it believes that retrospective attribution plus the provision of some beneficiary data is a more balanced option because it provides the ACO with more meaningful information about its expected assigned population before the performance period begins.

While we appreciate CMS' proposal to use the combined approach to help provide information about an ACO participating Medicare beneficiary prior to the performance year, we support the prospective rather than retrospective assignment of beneficiaries. Also, we do not support this option because retrospective attribution is particularly problematic, since neither the patient nor the physician knows that CMS is assigning accountability to the physician for the costs of all of the patient's care until after the care has already been delivered. Further, the Academy is concerned that the assignment of Medicare beneficiaries to an ACO which are not known in advance would require substantial market power to control costs. It is unlikely that the majority of our members, largely made up of small physician practices, will be able to obtain substantial market power required to form an ACO. However, even if they were able to gain market power, obtaining substantial market power may lead to anti-trust concerns. As a result, these small physician groups would need to spend additional funds to retain lawyers to review the anti-trust issues and implications. It is also uncertain how an ACO would be able to track its performance quarterly if it does not know who the enrolled beneficiaries are and where the ACO should direct its limited resources for improvement, if the focus for the improvement is not known. In a prospective model of enrollment, the ACO develops targets based on actuarial analysis and allows for all payers to agree upon such targets.

II. E. Quality and Other Reporting Requirements

Quality Measures for Use in Establishing Quality Performance Standards that ACOs Must Meet for Shared Savings

The Academy appreciates CMS' willingness to seek comment on the implications of including or excluding any proposed measures and whether the list of proposed measures should be narrowed. **The Academy is disappointed to see that there are no surgical measures proposed or measures specific to otolaryngology. The exclusion of such specialty-specific measures will hinder participation by otolaryngologists in ACOs or impact ACOs inclusion of otolaryngology in the ACO.** This would be counterintuitive to the goal of ACOs of improving quality and care coordination. Hearing loss is one of the most common



conditions affecting older adults. One in three people older than 60 and half of those older than 85 have hearing loss.¹

The following otolaryngology specific PQRS and/or NQF endorsed measures should be included:

PQRS Measure 91, Acute Otitis Externa (AOE): Topical Therapy

PQRS Measure 92, Acute Otitis Externa (AOE): Pain Assessment

PQRS Measure 93, Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy Avoidance of Tympanic Membrane Mobility

PQRS Measure 94, Otitis Media with Effusion (OME): Diagnostic Evaluation Assessment of Tympanic Membrane Mobility

NQF 0655 Otitis Media with Effusion: Antihistamines or Decongestants- Avoidance of inappropriate use

NQF 0656 Otitis Media with Effusion: Systemic Corticosteroids- Avoidance of inappropriate use

NQF 0657 Otitis Media with Effusion: Systemic Antimicrobials- Avoidance of inappropriate use

As a way to address a large portion of surgical care, **CMS should include the PQRS Perioperative Care measure group.** While the measure group is not applicable to all surgical care it is a universal measure group that can be reported on across surgical specialties. The following measures make up the Perioperative Care Measures Group:

Measure 20, Perioperative Care: Timing of Antibiotic Prophylaxis

Measure 21, Perioperative Care: Selection of Prophylactic Antibiotic

Measure 22, Perioperative Care: Discontinuation of Prophylactic Antibiotics

Measure 23, Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis

The Academy urges CMS to allow for more flexibility in meeting the ACO Quality Performance Standard. Having ACOs report on all 65 quality performance standards and at 100% is an unrealistic performance threshold, especially if you are a start up ACO and just putting in place a quality improvement program. The initial 65 measures are too many, as these measures will require different data sources and reporting processes to gather and submit the data. 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 because of the high reporting burden, or fail to succeed because of that burden. In order to improve quality, an organization needs to start with a focused area and then expand once they have met initial benchmarks. It is more appropriate for ACOs to explain to CMS how they plan to institute their quality improvement program and what specific disease areas they plan to target.

¹ *Hearing Loss and Older Adults*, National Institute of Health-Deafness and Other Communication Disorders, <http://www.nidcd.nih.gov/health/hearing/older.htm>.



The Academy 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. This will allow ACOs to choose measures that are the most relevant to the patient population they treat.

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.

E.3. Requirements for Quality Measures Data Submission by ACOs

Certified EHR Technology

The Academy agrees with CMS' intent to align the quality measures "currently included in the EHR Incentive Programs and [to] continue to further align the measures between the two programs." However, the Academy has concerns with aligning the program too prematurely because there currently are no otolaryngology-specific quality measures in the EHR incentive program. The Academy has advocated for inclusion of otolaryngology quality measures, but CMS has yet to incorporate them, which is a hindrance to otolaryngology participation. The Academy is also concerned with alignment because we do not know what the EHR Meaningful Use incentive program requirements will be beyond Stage 1. CMS must keep in mind when moving forward with alignment the possible affect this will have on specialty physicians and to not prevent specialists from being able to meet the requirements.

E. 4. Quality Performance Standards

Quality Threshold

CMS' proposed quality reporting mechanism requirements are unrealistic and the Academy believes CMS should adopt Option 2, *Quality Threshold* based on our experience with PQRS. For the first year, CMS is proposing 100 percent reporting on all measures before an ACO is eligible to share in any savings. The Academy urges CMS to apply more flexibility in this requirement. It is extremely difficult for a practice to achieve 100 percent on a quality measure. 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. CMS' argument that there is "no incentive to continue improving quality" once the ACO meets the performance target is false. Physicians do



not provide one level of care for patients during one period of time and then halt all quality improvement activities. Putting a quality improvement program in place, requires significant alteration of practice processes and would need to continue once the practice meets the threshold.

From experience with initial PQRS program years, the Academy found that errors can occur with the capture, transmission, and evaluation of quality measurement data. The majority of errors with PQRS are related to coding or inappropriately reporting on a quality measure. For example, the measure is meant to be reported on a patient older than 70, but the practice accidentally documents and submits the measure to CMS on a patient younger than 70 or submits the incorrect CPT II code on a claim. These types of errors are not lapses in quality, but reporting errors. The lower threshold will allow start up ACOs the opportunity to develop a quality improvement program and experiment with what works best for them. In addition, 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. Furthermore, the fifty percent threshold is in line with PQRS requirements, where physicians only have to satisfactorily report on a measure fifty percent of the time.

E. 5. Incorporation of Other Reporting Requirements related to the Physician Quality Reporting System and Electronic Health Records Technology

PQRS Group Practice Reporting Option Under the Shared Savings Program

The Academy seeks clarification on the proposed PQRS group practice reporting option under the Shared Savings Program, specifically ACOs submitting data on behalf of the eligible professionals in an effort to qualify for the PQRS incentive as a group practice and not qualifying as individuals. Since there are no otolaryngology specific measures in Table 1, if an ACO includes a specialist that cannot report on all the quality measures because it is not applicable to them would the specialist still qualify for the PQRS incentive or would it be up to the ACO to distribute the PQRS incentive to the specialist? Based on the proposed requirements, physicians who are part of an ACO are excluded from participating in PQRS independently.

E.6. 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 sub-regulatory guidance. CMS requests comments on these proposals.

The Academy 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 sub-regulatory 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 Academy 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. 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.

II. G. Two-Sided Model

- 1. Risk-Based Payment Models and**
- 2. Two Tracks Provide Incremental Approach to Incorporating Risk**

PAYMENT AND RISK STRUCTURE



The Academy is in support of the AMA comments regarding the payment and risk aspects of the Shared Savings Program. We recommend that CMS provide a payment option that includes shared savings only (“one-sided risk”) without the mandatory shared loss provision and that there should be an option allowing ACOs to receive shared savings, without the down-side risk. 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 placing them 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.

The Academy believes that small ACOs and physician-driven ACOs are at a disadvantage to accept down-side risk, particularly during the initial implementation stage of ACOs. Several reasons why it is *inappropriate* to force all ACOs, particularly small ACOs and physician-driven ACOs, to accept downside risk include lack of data, retrospective assignment of patients and lack of a supportive benefit design, lack of risk-adjustment, and costs driven by non-physician providers (as discussed in more detail in the AMA comment letter).

Further, we believe that in general, CMS should implement effective risk-adjustment methodologies and caps on the costs associated with individual patients so that ACOs are managing performance risk, not insurance risk. Any payment model that CMS implements should use an effective risk adjustment methodology so that ACOs are rewarded, not penalized, for accepting sick patients and for addressing their needs in the most effective way possible. But risk adjustment alone is not enough because some patients will have unique problems that require unusually expensive care not adequately captured by any risk adjustment methodology. Even a single patient of this nature could be financially devastating for a small physician practice, while having a relatively small impact on a large health system. ***Thus, in addition to appropriate risk adjustment methodologies, CMS should establish limits on an ACO's accountability for the total cost of services to any individual patient. CMS should also provide timely and detailed feedback to physician practices to enable them to identify opportunities to make improvements in cost and quality and to successfully implement them.***

V. Regulatory Impact Analysis

C. Anticipated Effects

3. Impact on Providers and Suppliers

In the proposed rule, CMS used information from a Government Accountability Office (GAO) report (GAO-08-65) on the Physician Group Practice Demonstration (PGP) to estimate aggregate costs for start-up investments and first year operations necessary for a new ACO.



Although CMS notes that information from the GAO report demonstrates that the expected range of investment varies greatly across ACOs and that the PGP-related costs may be a subset of the investment required for an ACO, the estimate of start-up costs of \$1.7 million are staggering to small physician practices which comprise most of our members in the office-based setting. Almost half of office-based practices are made up of 5 or fewer otolaryngologists-head and neck surgeons. And over the past 10 years, the median practice size in the office-based setting has remained relatively consistent at 3 otolaryngologists-head and neck surgeons. [Data taken from the AAO-HNS 2011 Socioeconomic Survey] There are a few members in larger groups who may be able to participate, but even those few would have to invest significant funds to participate in the Shared Savings Program. It is important to note that in the PGP, all 10 participants lost money in the first three years, and only 6 out of the ten had achieved even the 2% savings threshold, excluding start up costs after 3 years. Relatively small entities are technically eligible to participate in the program, but must achieve higher savings in order to share the money. Considering the start up costs involved, 20% savings over 3 years is needed to simply break even. The PGP demonstration participants were uniquely suited for the ACO-type model since they involved relatively large entities, were already highly integrated, were able to sustain financial losses, and had significant EHR use prior to the demonstration. It will be very difficult for small groups of physicians to participate, possibly leading to excluding some specialties from participating at all, decreasing choice and reducing competition that can help restrain costs for private payers. Besides start up costs, physicians may not be able to construct a feasible business case for the investment of capital even if they are able to get access to financial reserves or lines of credit extended from banks. Also, administrative burden on physicians with additional paperwork, forms required, etc, add to costs of the program. ***Therefore, we are concerned that the extraordinary investment and start-up costs involved in the Shared Savings Program will limit small physician specialties and potentially exclude specialties, including the majority of our members, from participating in the program and we urge CMS to address this issue in the final rule.***

Conclusion

We appreciate the opportunity to comment on the proposed rule. If there are additional questions and/or comments regarding our comments we encourage CMS to contact us. Again, the Academy would like to thank you for providing us with the opportunity to comment and looks forward to working with CMS and response to our comments in the final rule.

Sincerely,

David R. Nielsen, MD
Executive Vice President/CEO