



MASSACHUSETTS MEDICAL SOCIETY

Every physician matters, each patient counts.

June 6, 2011

Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

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

Dear Dr. Berwick,

The Massachusetts Medical Society, which represents over 23,000 physicians, students and residents, appreciates the opportunity to comment on CMS' proposed rules to implement Section 3022 of the PL 111-148 to create Medicare Shared Savings Programs. As you know the MMS has been immersed in efforts at the state level to implement delivery system reforms following passage of our historic state law providing universal access to health insurance. We are learning a great deal in that process; lessons that we believe are relevant to your deliberations. To that end, the following comments will share our general observations and approach to these initiatives before commenting on specific areas of concern in the proposed rules. We are eager to work with you and your colleagues as we move forward to meet our mutual goal of improving access to quality, cost effective, patient centered health care to all of our patients.

General

Arguably there is no issue more compelling or challenging than how to improve the quality of health care while controlling costs. In Massachusetts, where 97% of our residents now have health insurance, we are grappling with proposals to make our delivery and payment systems more cost efficient while providing higher quality, coordinated health care. Our physician members represent the gamut of health care groups. These include physicians who work for, or increasingly, may be employed by, large integrated systems which successfully manage risk, to about 62% of our practices which consist of only one or two full time physicians.¹ Within those parameters are a wide range of models, including small independent practices as well as those that are part of large well integrated networks.

¹ Commonwealth of Massachusetts. 2009. *Recommendations of the Special Commission on the Health Care Payment System*. Appendix D.14., p. 314.

As you are keenly aware, physicians are extremely reluctant to change their practice patterns unless they are certain there will be no harm to, or compromising of, the care they provide to their patients. Physicians will be particularly skeptical and predictably antagonistic to any reform where they perceive concerns about cost either trump quality or disrupt the patient-physician relationship.

Our goal, at both the federal and state level, is to work with all stakeholders - our physicians, patients, the health care delivery team, hospitals, payers, legislators and policy leaders - to foster a system which concentrates on providing the highest quality, cost efficient care to our patients. We believe a better coordinated system, which is led by physicians and focuses foremost on the care of the patient, can achieve the “three part aim of better care for individuals, better health for populations and lower growth expenditures.” We know that physicians have a singularly important role in that process. It is from this perspective that we believe that physicians must be at the center of the decision-making in these systems. Payers and others whose primary responsibility is the financing of care should not govern clinical decisions or care models. To help guide us through this process the 2011 Annual MMS House of Delegates developed a resolution which outlines the fundamental principles for health care reform.

MMS Principles on Health Reform

1. **Physician leadership.** Physician leadership is seen as essential for the implementation of new payment reform models. Strong leadership from primary care and specialty care physicians in both the administrative structure of accountable care organizations (ACOs) and other payment reform models, as well as in policy development, cost containment and clinical decision-making processes, is key.
2. **One size will not fit all.** One single payment model will not be successful in all types of practice settings. Many physician groups will have a great deal of difficulty making a transition due to their geographic location, patient mix, specialty, technical and organizational readiness, and other factors.
3. **Deliberate and careful.** Efforts must be undertaken to guard against the risk of negative unintended consequences in any introduction of a new payment system.
4. **Fee-for-service payments still have a role.** While a global payment model could encourage collaboration among providers, care coordination, and a more holistic approach to a patient's care, fee-for-service payments should be a component of subset of any global payment system.
5. **Infrastructure support.** Sufficient resources for a comprehensive health information technology infrastructure and hiring an appropriate team of physician assistants, nurse practitioners, and other relevant staff are essential across all payment reform models.
6. **Proper risk adjustment.** In order to take on a bundled, global payment or other related payment models, funding must be adequate, and adequate risk adjustment for patient panel sickness, socioeconomic status, and other factors is needed. Current risk

adjustment tools have limitations, and payers must include physician input as tools evolve and provide enough flexibility regarding resources in order to ensure responsible approaches are implemented. In addition, ACOs and like entities must have the infrastructure in place and individuals with the skills to understand and manage risk.

7. Transparency. There must be transparency across all aspects of administrative, legal, measurement, and payment policies across payers regarding ACO structures and new payment models. There must also be transparency in the financing of physicians across specialties. Trust is a necessary ingredient of a successful ACO or other payment reform model. The negotiations between specialists, primary care physicians, and payers will be a determining factor in establishing this trust.

8. Proper measurements and good data. Comprehensive and actionable data from payers regarding the true risks of patients is key to any payment reform model. Without meaningful, comprehensive data, it becomes impractical to take on risk. Nationally accepted, reliable, and validated clinical measures must be used to both measure quality performance and efficiency and evaluate patient experience. Data must be accurate, timely, and made available to physicians for both trending and the ability to implement quality improvement and cost effective care. The ability to correct inaccurate data is also important.

9. Patient expectations. Patient expectations need to be realigned to support the more realistic understanding of benefits and risks of tests and clinical services or procedures when considering new payment reform models. Physicians and payers must work together to provide a public health educational campaign, with an opportunity for patients to provide input as appropriate and engage in relevant processes.

10. Patient incentives. Patient accountability coupled with physician accountability will be an effective element for success with payment reform. An important aspect of benefit design by payers is to exclude cost sharing for preventive care and other selected services.

11. Benefit design. Benefit designs should be fluid and innovative. Any contemplation of regulation and legislation with regard to benefit design should balance mandating minimum benefits, administrative simplification, with sufficient freedom to create positive transparent incentives for both patients and physicians to maximize quality and value.

12. Professional liability reform. Defensive medicine is not in the patient's best interest and increases the cost of healthcare. In an environment where physicians have the incentive to do less, but patients request more, physicians view litigation as an inevitable outcome unless there is effective professional liability reform.

13. Antitrust reform. As large provider entities, ACO definitions and behavior may collide with anti-trust laws. The state legislature may be the adjudicator of antitrust issues. Accountable care organizations and other relevant payment reform models should

be adequately protected from existing antitrust, gain-sharing, and similar laws that currently restrict the ability of providers to coordinate care and collaborate on payment models.

14. Administrative simplification. Physicians and others, who participate in new payment models, including ACOs, should work with payers to reduce administrative processes and complexities and related burdens that interfere with delivering care. Physicians should be protected from undue administrative burden, or should be appropriately compensated for it.

15. The incentives to transition. In order to transition to a new model, incentives must be predominantly positive.

16. Planning must be flexible. Accommodations must be made to take into account the highly variable readiness of practices to move to a new system.

17. Primary care physician. All patients should be encouraged to have a primary care physician with whom they can build a trusted relationship and from whom they can receive care coordination.

18. Patient access. Health care reform must enable patient choice in access to physicians, hospitals and other services, while recognizing economic realities.

Our specific comments on the rule follow.

I. Health Disparities, High-Risk and Chronically Ill Patients

ACOs must be appropriately designed to care for minority patients, patients with health care disparities, chronically ill patients and patients who are considered high risk given their health status.

In 2002 the IOM published “Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care,” which summarized the landmark finding that health care disparities exist even when minority patients are insured across corresponding socioeconomic classes. ACOs will need to be appropriately designed to care for these patients who will constitute the majority of our population in 2040. We must focus our efforts on supporting those physicians who take care of a disproportionate percentage of minorities and underserved patients. This issue is particularly relevant with respect to proportionality on patient-physician panels. ACOs should be assessed as to how well they incorporate a diversity of patients given the community in which they serve. This emphasis is essential to decrease disparities in health care. While this is complicated issue, which also involves workforce shortages, our efforts to improve quality and control costs will fail if a significant segment of our patients continues to receive fragmented care.

In addition, CMS must take into consideration the overall percentage of patients/providers and incorporate the “sickness of the patient panel” and socioeconomic indicators so as not to penalize those providers who have patients with a greater severity of illness or environmental challenges. There are no scientifically tested or proven risk adjustment techniques available at this time to

achieve this goal. Thus the imperative for CMS to develop such metrics with the physician community will be compelling, urgent and integral to the success of ACOs and other delivery system reforms. Section VI of this document provides detailed comments on the need for appropriate risk adjustments for multiple factors.

II. Governance

The proposed rules state that an ACO must form a governing body that operates a program that includes the hallmarks of a clinical integration program. These include: a board-certified physician, licensed in the state in which the ACO operates, to serve as medical director with clinical management and oversight; a physician directed quality assurance and process improvement committee; development and implementation of an evidence-based medical practice or clinical guidelines processes; and an infrastructure to enable collection and evaluation of data and feedback across the entire organization. If a potential ACO applicant does not have an existing governing body that includes representatives of all ACO participants (i.e., hospitals and physicians), it must form one. ACO participants must hold at least 75% control of the governing body. The ACO governing body also must have direct representation of a Medicare beneficiary. ACOs must submit in its application to CMS a description of its processes to promote evidence-based care, patient engagement, and reporting and care coordination. The governing body is ultimately responsible for executing the functions of the ACO, promoting evidenced based medicine within the ACO, engaging ACO patients, reporting on quality and cost measures and coordinating care.

The MMS strongly believes that physician leadership is essential for the implementation of any new delivery system model including Accountable Care Organizations. Strong leadership from both primary care and specialty care physicians in the administrative structure of Accountable Care Organizations and other payment reform models, as well as in policy development, cost-containment and clinical decision-making, is critical.

Physicians are the medical professionals best qualified by training, education and experience to ensure proper diagnosis and treatment of patients. Physician leadership in an ACO can encourage collaboration among physicians to ensure that medical decisions are made by physicians based on the best interests of the patients' health while respecting cost efficiencies.

Studies of successful physician networks have demonstrated repeatedly that physician leadership within an ACO type organization is critical to their success. During the past year the MMS has convened several focus groups with our large integrated systems to analyze their programs. Each group emphasized that physician leadership and commitment to the system was crucial.

The MMS supports meaningful collaboration among physicians, hospitals and other qualified providers as long as the governance of those arrangements ensures that physicians are the final arbiters of clinical decision-making. ACOs should be operationally structured and governed accordingly. The ACO should be governed by a board of directors which is selected by the ACO professionals and includes a substantial number of physician representatives. Any physician-entity, such as an IPA, that contracts with or is part of an ACO, should be physician controlled and governed by an elected board of directors. We support CMS' proposal that ACOs 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 concerned that the requirements for the governance structure might be too burdensome for smaller groups and thus serve as an impediment to these groups forming an ACO. We encourage CMS to explore other models where the governance structure is shared among organizations thus allowing efficiencies of scale for legal and other costs.

III. Beneficiary Assignment

The proposed rule states that ACOs must have a minimum of 5,000 patients. Beneficiaries will be assigned to an ACO based on the primary care physicians from whom they receive the plurality of services as defined by Medicare charges. Primary care is defined as internal medicine, general practice, family practice and geriatric medicine. CMS proposes to assign patients retrospectively to ACOs after one year. Primary care physicians can only belong to one ACO for the first three years; all other physicians and providers can participate in multiple ACOs.

We have a number of concerns regarding beneficiary assignment.

1. **We have strong concerns about retrospective assignment of Medicare beneficiaries to an ACO.** This approach undermines the basic tenets of coordinated, integrated care and patient choice. Just as physician participation in an ACO is voluntary, patients should be afforded the initial choice of selecting their physician with the knowledge they are participating in an ACO. Patients who choose to receive their care from an ACO should also be educated as to how an ACO operates, their systems for improving the quality, coordination and cost of care, and the patient's role and responsibility in that process.
2. **In addition to aggregated data on Medicare beneficiaries in the region, ACO providers should be given timely, accurate and detailed Medicare data on the beneficiaries who choose to participate in the ACO.** The only way to accomplish this is to know which Medicare beneficiaries are going to participate in the ACO.

Currently the NPRM proposes giving the ACO "proxy" data on Medicare beneficiaries who might be part of the system. We believe it is critical that physicians participating in any risk contract, whether through Medicare or a private payer, obtain detailed information on their patients care patterns and utilizations. Private payers vary in their ability to deliver such information, but the amount of data and information made available is expanding rapidly as more risk contracts are being established. The Massachusetts Blue Cross-Blue Shield Alternative Quality Contract for example, shares a detailed report with their providers about their patients. Providers are in critical need of this information to improve care and cost efficiencies. Unless the beneficiaries are new to Medicare, CMS already has significant data on these patients.

3. **Assigning beneficiaries on a retrospective basis over a period of time is also problematic because health status can change quickly and patients often wish to change physicians**

during the year based on these changes. Attributing patients to an ACO retrospectively may not provide a valid picture of the physician's patient base over a period of time. Coupling these shifts across multiple physicians within an ACO increases the risk that retroactive patient data may distort the true profile of an ACO's practice.

4. **The proposed attribution method in the proposed rule, to assign patients based on the “plurality” of PCP payments over the prior three year, is flawed.** A group could be assigned patients' for whom only 20% of the primary care had been provided, if no other group provided a higher tally. This scenario happens commonly with some patients and is not a viable formula to attribute risk for an ACO model. We recommend that CMS consider a different measure for assigning patients to an ACO; for example a patient would not be considered a participant in the ACO unless 50% of their primary cares visits were through a particular ACO.

In addition, there should be a process for physicians to appeal attribution of a patient to their ACO.

5. **One of the most difficult issues that we will need to address throughout this process is how to enable patient choice, while recognizing the financial goals that an ACO model promises to achieve. Our recently approved MMS principles state: “Health care reform must enable patient choice in access to physicians, hospitals and other services, while recognizing economic realities.”**

We believe patients must be allowed to make an informed choice of their physician, and if they so choose, an ACO. This is critical to both the potential success of an ACO and the patient's health care. The proposed rule currently states that patients can seek care from any organization, including providers that are not within the ACO. The MMS strongly supports patient's freedom of choice and believes this should be protected. At issue are the cost implications, which are one of the primary and driving forces behind the movement towards an ACO. Experience and data have shown that groups which successfully coordinate care improve quality and control costs, strive to keep their patients care within an identified network. The issue of voluntary patient engagement in the ACO is critical and reaffirms the need to give patients the choice up front with respect to their physician and health care delivery system.

6. **The MMS strongly believes that all patients should be encouraged to have a primary care physician with whom they can build a trusted relationship. For some chronically ill patients, we would suggest CMS consider that assignment to an ACO be based on the relevant physicians, who may or may not one of the primary care physicians designated in the NPRM.** For many of these patients, their ongoing care is provided by a specialty physician who may also provide their primary care.

7. We are concerned about the proposed rules provisions to allow beneficiaries to “opt-out” of data sharing

The MMS is a strong advocate of protecting patient privacy and confidentiality. However we do have concerns about some of the implications of this provision. One issue is the actual mechanics of how the “opt-out” status will be tracked and maintained. The “opt-out” theoretically will occur at the point of care delivery (i.e. the physician’s office) and then must be communicated to CMS whose data contractor will maintain a running list of all the patients that have chosen to “opt-out” of having their data shared. We are also concerned that while a patient may “opt out” of having their data shared with an ACO, the ACO will still be held accountable for the costs of care to those patients. Effective coordination of care, and resultant cost savings, cannot be achieved without timely access to comprehensive and accurate patient data.

IV. Quality Measurement Requirements are Excessive and Flawed

CMS proposes 65 quality measures for the first year from the following domains:

- Patient/Caregiver Experience of Care
- Care Coordination
- Patient Safety
- Preventative Health
- At Risk Population/Frail Elderly

For the first year ACOs would need to report on the 65 measures. In years two and three, the ACO will be evaluated on its performance on these measures. A performance threshold will be calculated based on the ACOs measurement scores. CMS will issue another rulemaking for Year 2 & Year 3 with new quality measurement requirements. ACOs which do not meet the quality measures and thresholds, regardless of their financial success, will not share in the savings. We have a number of concerns about the proposed quality measurement requirements.

1. We believe that sound quality measurements will be the key to success of this effort and delivery system reforms designed to improve patient care. **However, the proposed measures are inadequate for a senior population.** To be effective, these measures need to adjust for such issues as chronic illnesses, dementia and other conditions common to the senior population, not just age. Measures for transitions of care, pharmacy management, to name a few, should also be included. Outcome measures can be appropriate in the second or third year of the ACOS, but again need to be adjusted on a population basis.
2. **The total number of quality measures required in the proposed rule is excessive and will prove to be a significant obstacle for small physicians groups who have limited administrative resources to generate such reporting.** Reporting on quality measurements will also require a robust Electronic Medical Record System. As less than 20% of physicians currently have a complete EMR system, we believe leniency will be needed during the transition period. Significant investments in infrastructure will be required in most cases for

physicians to comply with these requirements. We recommend that total number of measures be reduced significantly.

3. **The law states that hospitals do not have to be part of an ACO, yet several of the quality measurements only apply to hospitals and inpatient care.** These quality measurements should only apply to ACOs that include hospitals. It should also be noted that while the majority of the quality measurements focus on ambulatory care, there are significant savings to be accrued from quality improvements in the inpatient setting.
4. **The proposed rule stipulates that no shared savings will be available unless the ACO reports on all of the quality measurements regardless of the savings achieved. We believe this language is unnecessarily punitive and will dissuade many groups from participating.** We received comments from a number of physician groups, including large groups who manage risk, that this is an unrealistically high standard. We are also concerned that the proposal to terminate ACOs which miss one of more quality targets for two years in sequence is overly strict.
5. **The quality reporting requirements for ACOs should be coordinated with the requirements for meaningful use, PQRI and other mandated reporting.** Otherwise we will have significantly increased the administrative burden on physicians' offices without a real improvement in quality performance.

We urge CMS to consider implementing quality outcome measures along a continuum with graduated levels of quality metrics, for example beginner, intermediate and advanced. These levels would appropriately scale the number and type of metrics an ACO would be judged on based on the level of existing experience, size and level of integration in this arena. This would allow those who are less advanced in the area of outcome measures to feel comfortable about engaging in the proposed shared savings program².

CMS also notes in the rule that the agency will engage in a separate rulemaking to develop future metrics for the quality measures that will include performance and outcomes. Given that no such metrics exist we believe the AMA and national physician community must be part of this effort. We also support ongoing evaluation of the effectiveness of the metrics to eliminate meaningless and burdensome measures for physicians and ACOs. We urge CMS to consider the important balance between outlining metrics in advance while allowing flexibility as the metrics are tested and implemented. ACO's will need additional lead time to comment on their worth and to incorporate them in their daily office settings.

²A National Strategy to put Accountable Care into Practice. Mark McClellan, Aaron N. McKethan, Julie L. Lewis, Joachim Roski and Elliott S. Fisher. Retrieved on May 27, 2011 from <http://content.healthaffairs.org/content/29/5/982/T2.expansion.html>

V. Provision of CMS Data

CMS is proposing to give aggregated data on the potential ACO beneficiaries to the ACO. Pending the ACOs request, CMS will provide historical data on the beneficiary population at the beginning of the first performance year.

As stated above, we believe comprehensive and actionable data from CMS regarding the actual risk profile of patients is key to any payment reform model. Without meaningful, comprehensive data it becomes impractical to take on risk. In addition to the historical data on potential ACO beneficiaries, we recommend CMS share data on an ongoing basis for the Medicare beneficiaries assigned within their ACO starting at the time of enrollment.

Nationally accepted reliable, valid, clinical measures must be used to efficiently measure quality performance and to evaluate the patient experience. Data must be accurate, timely and made available to physicians for monitoring trends and timely evaluation of the effectiveness of quality improvements and cost effective care delivery. The ability to correct inaccurate data is also important.

We have serious concerns about CMS' ability to ensure that data provided during the process of attributing Medicare beneficiaries to ACOs or as part of the quality measurement process will be accurate or timely. "One of the chief complaints of the 10 PGP participants was that CMS failed to provide timely feedback on utilization patterns and other data important for monitoring the use of resources." In an article published in the March 2102 New England Journal of Medicine, "Physician Cost Profiling: Reliability and Risk of Misclassification," researchers from RAND concluded: "These findings bring into question both the utility of cost-profiling for high stakes uses, such as tiered health plan products, and the likelihood that their use will reduce health care spending". Unfortunately we have extensive experience in Massachusetts with erroneous data. It will be critical that CMS outline the process in detail for the reporting and dissemination of all data, including an opportunity for physicians to correct the data as well as an appeals process if there is an unreconciled dispute.

VI. Payment and Risk Structures

The proposed rule establishes two types of the ACOs: Track 1 ACOs which are only responsible for downside risk in the third year, and Track 2 ACOs which are responsible for down side risk all three years. The NRPM also establishes a Minimum Savings Ratio (MSR) for ACOs. If the Track I ACO exceeds the MSR and meets quality performance requirements it can share in the savings up to 52.5%. The MSR for Track I will be greater than 2%. CMS proposes a shared savings cap, e.g., a cap on how much of the savings an ACO can retain. For Track 1 the cap is 7.5%. For Track 2 ACOs, if they exceed the MSR, the ACO can share up to 65% of the savings providing they meet the quality standards. The shared savings cap for Track 2 ACOs is 10%.

The proposed rule also establishes a formula for determining shared losses. If an ACO's losses are greater than 2% of their benchmark they will share in the losses. CMS proposes a shared losses cap. For Track I ACOs, which only assume down side risk in the third year, the cap on losses is 5% for year 3. For Track 2 ACOs, which assume down side risk all three years, the cap

is 5% year 1, 7.5% year 2 and 10% year 3.

To ensure ACOs have sufficient funds to pay back any losses, CMS proposes a 25% withhold annually to any earned performance payments. In addition to requiring ACOs to set up systems to automatically repay losses, including reinsurance and other methods, CMS will review ACOs solvency prior to each contract year.

We want to underscore that participation in these ACOs must be voluntary. The MMS believes that physicians who want to participate in these programs should be supported in this effort; however there are a significant number of practices for whom these models are not viable. The potential success of Medicare shared savings ACOs will depend on the flexibility of the model (one size does not fit all) along with incentives to help physicians and providers succeed in these efforts. These concerns are particularly significant for physicians whose practice focuses on delivering care to patients with health care disparities for whom resources are already tenuous. CMS is urged to encourage models that will appeal to those who have successfully managed risk and integrated care, as well as those practices that have not. We believe that an array of approaches to physician payment and delivery system reform should be voluntarily tested in Medicare and the private sector. This diversity is crucial.

It also important to reiterate, that we need to view this proposal as one step in an overall process to help physicians and other health care providers move toward a system that encourages more coordinated, cost efficient care. Medicare Shared Savings ACOs are but one model in that effort. Our overall goal to improve quality and control costs is not dependent on this one approach, but our ability to work with all physicians and patients to that end. **We also continue to see a role for fee for service payments within these coordinated systems of care.** There are many organizations and physicians currently participating in forms of global payment that do not necessarily represent a fully integrated accountable care organization. While those entities employ various degrees of global payment and risk, there is still a valid use for fee for service payments. We recognize that fee for service is the basis for payments in the one-sided models, but we also believe future models for ACOs should continue to recognize the role of fee for service payments for some physician specialties within these models.

We have a number of concerns with the two risk models proposed in the NPRM.

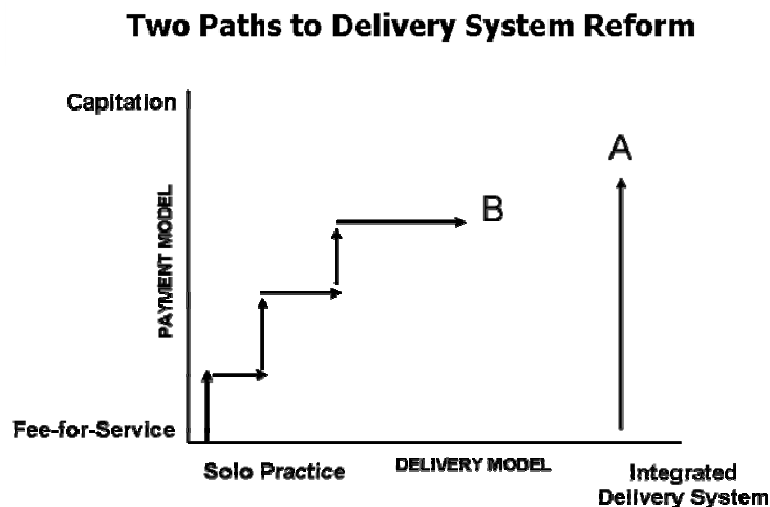
1. CMS should consider a variety of Medicare shared savings models including partial capitation, gradual movement to global payment with risk and other models.

Section 3022 of the Patient Protection and Affordable Care Act did not include a down side risk model for shared savings ACOs. We believe it was Congress' intent to encourage physicians and other providers to experiment with global payments without fear of negative financial consequences. The current proposal undermines this approach by only including models with down side risk, albeit limited in first option. We believe this will dissuade physicians and other providers from testing a shared savings or coordinated care model and further impede progress towards new delivery systems. The issue of managing risk, and learning how to proceed without significant penalty, will be particularly important to small, independent practices which have limited experience in this area. We strongly encourage

CMS to consider a variety of other alternatives to those proposed, including a no risk and/or partially capitated model. Kaiser notes that global care payments encourage people to work together but that moving toward global payments takes time and should happen incrementally for those providers not yet able to manage global payments. For these providers, Kaiser suggests a step-wise approach where systems can gradually move through different levels to get to global payments. Such an approach could involve keeping fee-for-service payments as you introduce different bundled payments (episodic payment models) for different episodes of care over 5-7 years. This allows the system to adjust and allows providers to buy in to the changes eventually allowing the system to move toward global payments for all of the care patients need.

Although this stepwise approach to implementation is needed in many situations, Dr. Jay Crosson, Senior Fellow at Kaiser Permanente Institute for Health Policy, notes that there are providers in Massachusetts and elsewhere who are ready now and could move toward global payments more quickly. Therefore, he suggests a simultaneous model of movement to global payments (as depicted in Figure 1 below) which would have concurrent tracks.

Figure 1:



Moving too quickly to shared savings with downside risk will be difficult for providers who lack both the resources and infrastructure to manage global payments. CMS should consider a combination of FFS and episodic payment models for those not ready for full risk as one of the shared savings models.

2. The Calculation of the Benchmark Should be Risk Adjusted for Multiple Factors

The law requires CMS to estimate a benchmark for each ACO using the most recent available three years of per beneficiary expenditures for Parts A and B services for Medicare fee for service beneficiaries assigned to an ACO. This benchmark must be adjusted for beneficiary characteristics and other factors that CMS determines appropriate. Savings thresholds will be derived from these benchmarks.

The accurate calculation of the benchmark is one of the critical factors in the proposed shared savings formula. Overall the benchmarks should be adjusted for differences in geographic practice costs and risk adjusted for individual patient risk factors.

- a. **The ACOs benchmark, which will be based on historical spending patterns in the ACO's service areas and negotiated between Medicare and the ACO, must be risk adjusted in order to incentivize physicians with sicker patients to participate in ACOs and incentivize ACOs to accept and treat sicker patients.** The proposed rule only suggests risk adjustment for case mix severity for the baseline patient group and not for subsequent years. Since there may be significant fluctuations in morbidity over time, we propose that risk adjustments be incorporated into the cost savings analysis for each program year.
- b. **The ACO benchmark should be risk adjusted for socio-economic and health status of the patients that are assigned to each ACO, such as income/poverty level, insurance status prior to Medicare enrollment, race and ethnicity and health status.** Studies show that patients with these factors have experienced barriers to care and are more costly and difficult to treat once they reach Medicare eligibility.

Minority patients and patients in underserved areas often have more advanced and/or chronic illness. In these communities, patients with hypertension are more likely to have complications such as stroke, renal failure and heart disease as a result of poor access to care and lack of treatment in the early stages of the disease process. These patients would need a comprehensive risk assessment before they are put into ACO's or contract risk pools. Adjustments for multiple factors would need to be taken into account. We also know that the distance to providers, problems with transportation, social and cultural barriers, including language difficulties, are all significant barriers to timely care. Access to primary care providers is limited for these patients, who also experience prolonged wait time to see specialists.

We have serious concerns about the ability of these models to care for communities where health disparities exist. In addition to creating the necessary infrastructure for care, regional data for a given population where disparities exist would be needed to risk adjust for these patients.

CMS must consider also an index to take into consideration the overall percentage of CMS patients/providers and incorporate the "sickness of the patient panel" and socioeconomic indicators so as not to penalize those providers who have patients with a greater severity of illness or environmental challenges.

- c. **The ACO benchmark must be adjusted for geographic practice costs, such as physician office expenses, related to rent, wages paid to office staff and nurses, operating costs, hospitals operating costs and physician HIT costs.** The cost to run a medical practice in Massachusetts is higher than the national average due to the cost of labor and rent. For example, in 2009, an analysis of office

wages and rent found that composite office wages were about 25% higher in Massachusetts compared to the U.S. while average office space rental costs in Boston exceeded the U.S. average by 17%.³ These costs must be accurately figured into the ACOs formula.

d. The ACO benchmark should include a reasonable spending growth rate based on the growth in physicians and hospital practice expenses as well as the patients socioeconomic and health status factors.

e. The ACO benchmark must account for efficient practices which are already managing risk.

We are concerned that this formula will penalize efficient groups who have already significantly reduced their costs to Medicare beneficiaries. This is a particular problem for those IPAs and other organizations which have managed risk for several years and would presumably be more interested in participating in the Medicare shared savings model. The issue of how to tailor this proposal to appeal to groups which have managed significant risk as well as those who have not will be critical to its overall success in fostering delivery system reforms.

f. ACO benchmarks must take into consideration temporal changes which introduce wide variations in health care costs, for example epidemics, regional public health and natural disasters.

An alternative approach would be to set a threshold, perhaps several percentage points below the average area per capita costs for Medicare, so that groups would be working on a level playing field. CMS should also evaluate giving bonuses to those groups that spend less than the national average per Medicare beneficiary, accounting for variations in practice costs, geographic variation, case mix and other factors.

3. Calculation of the Minimum Savings Threshold Should Include Investment Costs in the ACO Infrastructure

The NRPM currently proposes that savings and losses are based only on Medicare FFS payments, and does not include infrastructure, case management, insurance and other investments an ACO may need to make. We believe this is a significant problem and will only exacerbate the problems for small groups who are interested in forming a Medicare Shared Savings ACO. Unless corrected, this proposal will only potentially appeal to well developed large integrated systems, although even those groups have expressed significant concerns about the proposed rule's excessive quality requirements and financial limitations.

4. Downside Risk in the Third Year is Unrealistic

Based on our experience, the proposed three-year time line for ACOs to assume risk and or show savings is unrealistic. Writing in the March 23 New England Journal of Medicine,

³ Massachusetts Medical Society. 2011. *Physician Practice Environment Index*.

Trent Haywood and Keith C. Kossel studied the CMS Physician Group Practice Demonstration projects (PGP). As you know the PGP Demonstrations ran from 2005-2010 using a hybrid payment model that consisted of Medicare fee for service payments with an opportunity for bonus payments known as shared savings. Eligibility was narrowly restricted to a select group of large physician group practices with the necessary experience, infrastructure and financial strength (e.g., participants invested \$1.7 million on average in the first year) to succeed. While the authors acknowledged some limitations to their study, they found that most of the PGP participants did not break even on their initial investment.

The article states:

“The available data indicated that 8 of the 10 PGPs in the demonstration did not receive any shared savings payments in year 1. In the second year, 6 out of 10 practices did not receive such payment, and in the third year, half of the participants were still not eligible for any shared savings to offset their initial investment. *Given that the percentages of shared savings in the first 3 years were so low for experienced, integrated physician practices, it seems highly unlikely that newly established, independent practices would be able to average the necessary 20% return on their investment.*”

A similar lesson is learned from the Geisinger system. Geisinger implemented global capitation during the 1980s but shifted from this form of payment in the 1990s to a modified form of primary care capitation after Geisinger experienced financial losses from its capitated arrangements. As costs associated with the provision of care increased, including ancillary, inpatient, and pharmaceutical costs, the GHP began losing money through risk sharing making capitation payments unfavorable.⁴ According to Geisinger, the downside risk associated with capitated arrangements has been difficult for physicians as they are often unprepared to deal in a full risk. In the past, capitation has caused significant financial losses to both the health insurance plans and physicians.⁵

Even now, Geisinger, a fully integrated large health care system, has not put downside risk on their physicians, when implementing global payment models. Geisinger uses a blend of payment methods including global payments under a shared savings model to provide medical home services to its patients.⁵ Under global payments for medical homes, physicians are given a set budget and a target for shared savings in caring for a group of patients within the medical home model.⁵ To calculate the shared savings amounts, a target is set by GHP by estimating medical expenses for a practice that includes rate of inflation. If the practice is able to generate efficiency savings to beat the target, they split the savings with GHP 50-50. For example, if the GHP expects a 5% increase in medical expenses for a practice, it sets the efficiency savings target at 5%. If the practice ends with only a 3% increase, the practice's efficiency efforts are considered successful and the remaining 2% in savings is split between the clinic and the GHP after physician and practice stipends are deducted.⁵

⁴ Geisinger shifts from global to primary care capitation. *Capitation Management Report*. July 2003: 10(7); 93-95.

⁵ Personal Communication. Teresa Willard. Vice President, Provider Network Management. Geisinger Health Systems.

Geisinger stresses that it is not trying to ratchet down medical expense with this model; it is trying to promote efficiency and bend the cost trend. Geisinger believes that this practice promotes efficiencies without putting downside risk on the physician or the practice, and stresses that it wants to generate enough improvements in efficiency savings to cover all of the advances being developed in health care. Therefore, in addition to efficiencies by physicians, payments are provided to mid-level practitioners, as well as practice office staff, so that all staff involved in the medical home are rewarded for efficiency while quality indicators are also reviewed by management to incent providers.⁵ Data shows that the medical home initiative has resulted in a 20% reduction in hospital admissions and 7% savings in total medical costs. All pieces of the model are interconnected to decrease the per-patient, per-month expenses.

Haywood and Kosel recommend that a more inclusive approach to fostering Shared Savings ACOs would be to change the payment design from an annual model to a cumulative model. Under this approach CMS would assess the performance of the organization over an aggregate number of years and reduce the shared savings threshold making it more likely that physicians could demonstrate significant improvements. Analyzing performance over time, rather than one year in isolation, would minimize the impact of a bad year and allow the providers to show improvement over time, which is the ultimate goal of these changes. If downside risk is transitioned inappropriately and too quickly to providers, the inevitable effect on patients will be restrictions of access to necessary services and rationing of care.

5. 25% Withhold is Too High

The proposed rule states that a 25% withhold would be applied to the shared savings payment to ensure that adequate funds are available to cover any losses. It is unclear how this would work since presumably shared savings would only be paid if the ACO demonstrated savings over the 2% threshold. It would be unrealistic if CMS is suggesting that the withhold would be applied to each ACO to ensure the losses for all other ACOs would be covered.

We believe it will be even more difficult for a new or smaller ACOs to succeed with a 25% withhold. As an ACO grows, the 25% withhold could inadvertently cap their ability to re-invest in the infrastructure critical to an ACO's success. This requirement would be extremely prohibitive for disproportionate care physicians, working in the urban as well as rural areas. A 25% withhold well exceeds the operating margin of most physician practices. Even if only one half of a provider's patient population is comprised of CMS beneficiaries enrolled in an ACO, this would result in a 12 1/2 % decline in gross operating income, threatening the financial viability of small medical practices that are already at the brink of financial ruin. In short, the 25% withhold doesn't necessarily improve quality but, in fact, penalizes the best performing ACO's with little or no impact on the poorest performing ones.

In lieu of this provision, we recommend that CMS consider requirements that individual ACOs have sufficient reserves and or reinsurance to cover specific losses.

VII. Funding and Resources for Infrastructure Improvements are Essential (IT and Personnel)

CMS estimates in the proposed rule that it will cost approximately \$1.7 million to start up a Medicare Shared Savings ACO - the same level of investment made by practices in the PGP demonstrations.

We believe it is critical that CMS find resources to help practices develop the necessary infrastructure to better coordinate care and participate in an ACO, if they so choose. While we value the recent announcement from CMS regarding new initiatives from the CMMI to fund alternative initiatives, we do not understand the rationale for prohibiting CMMI projects from being integrated with the Medicare Shared Savings Projects.

Geisinger Health Plan (GHP) provides Geisinger Clinic physicians with a physician stipend. These physician stipends ensure physician engagement in medical home participation. The GHP provides “system-based care payments” as practice stipends. These monthly amounts, provided to each medical home site, fund infrastructure changes, an essential ingredient for practices migrating to payment reform given that many practices do not have the budget to pay for medical home model infrastructure essentials, such as telephone systems, nurse education, an EMR with Internet functionality. Therefore, the GHP practice stipends help remove infrastructure barriers that may impede a practice’s ability to successfully implement a medical home model.⁵

The physician stipends and system-based care payments (practice stipends) are funded from future efficiency savings. At the end of a target period, GHP examines efficiency savings after netting out the physician and practice stipends. The remaining money is split 50-50 between the GHP and the Geisinger clinic. GHP pays for case managers out of their own 50% because Geisinger clinic practices and physicians are often not in a position to budget for this type of expense.⁵

On a recent Modern Healthcare Webinar about ACOs, the Advocate Healthcare representative, Dr. Mark Shields, noted that their ACO model at the system level hired 70 FTEs (over a period of time) focused on care management to ensure that physician orders were being carried out upon discharge from each of the 10 hospitals within the system. Although the Advocate system did not employ small practices, there was a decided benefit for small practices to align themselves with the system both for care management support and access to technology⁶.

The complexity of care management, disease management and coordination of care, coupled with managing and reporting 65 metrics, is daunting to even the most organized groups. The key to success in the ACO environment is physician willingness to truly communicate and partner with parties at each juncture of the patient care pathway as decisions, which were perhaps once viewed as tangential, will now impact the physician and the ACO. A true structure around metrics reporting and collaborative communication across entities whether internal or external to the ACO is crucial. Our concern is that the investment necessary for a small practice to participate in the shared savings program will essentially price these practices out of the system.

⁶The Next Steps in Accountable Care Organizations: The Promises and Pitfalls for Providers and Payers in Operating an ACO. Modern Healthcare Webinar. Accessed at <http://www.modernhealthcare.com/assets/pdf/CH73386330.PDF>, April 2011.

We urge CMS to work with the physician community to explore funding sources to invest in the infrastructure, information technology, care management, and related infrastructures that will be critical to the success of physician's practices.

VIII. Patient Experience Measures

The proposed rule outlines quality measures for the patient's experience. We believe a patient's active participation in the ACO is extremely important. There is also a parallel issue of how patient noncompliance will be figured into the ACO's success/loss ratio. Physicians and other providers will be measured on performance measures which will clearly be impacted by a patient's compliance with treatment protocols. In risk-based models, a patient's compliance and willingness to participate in the systems designs is an important component of the model's success. To this point we believe it will be critical that CMS both incent ACOs to educate their patients about the ACO model, their role in the process, and how systems are designed to better coordinate care and provide a higher quality of care.

CMS is also encouraged to develop a standardized tool to measure patients' experiences which acknowledges some of the limitations of patient satisfaction tools. Data elicited from these tools can be a reflection of patient expectations rather than a true determinant of quality. We also recommend that physicians be able to review a patient's comments retrospectively which could serve as an important educational instrument. On a single visit with difficult news, the patient might rank the visit very poorly. Consideration should be given to how these factors would impact the patient review.

IX. Health IT Requirements

CMS proposes that in year 2 of the ACO agreement "at least 50 percent of an ACO's primary care physicians" are "meaningful electronic health records users."

Many of the efficiencies of an ACO ride on the cohesion and participation in sharing clinical data. A fully integrated electronic medical record system is a critical tool in this process. However there are several barriers to this goal which must be addressed by CMS.

1. EMR utilization varies widely.

Estimates range from less than 20% of primary care physicians using EMRs to some systems where there is 100% compliance with meaningful use requirements. If the new Medicare Shared Savings ACOs are to appeal to potentially newly formed groups, as well as established networks, we remain concerned that the 50% threshold is too high for primary care providers. Resources to help physicians invest in these systems will be critical.

It also important to emphasize implementation of HIT systems is more limited in communities with health disparities. The highest penetration of EMRs in underserved populations is in community health centers linked to academic institutions. Such systems will be essential in managing high risk populations with a greater prevalence of chronic diseases.

2. The absence of interoperability is a major impediment

True structured-data interoperability (meaningful clinical data communication), transportability (moving from one brand of EMR to another) and Health Information Exchange (HIE) are not yet widespread. As communities form ACOs, there will most likely be a broad mix of EMRs as hospitals, large practices and small practices tend to buy completely different technology which is not currently compatible. Early adopters and early ARRA incentive recipients may be required to change their systems and buy whatever EMR the ACO standardizes on in order to participate. This will put many small practices and specialists at risk unless there is extra compensation for “EMR Harmonization.” In Massachusetts, the MMS joined with Blue Cross-Blue Shield and a number of other health care groups to create the Massachusetts eHealth Collaborative (MAeHC), which funded three-year demonstration projects to test the interoperability of electronic medical record systems in three communities across health care settings. The three MAeHC pilots proved that complexity in a community is the enemy of success in exchanging data.

The lack of interoperability between EMRs and the need for physicians to reinvest in new systems, “EMR Harmonization,” are significant impediments to the promise of ACOs and ultimately care coordination across health care settings.

Next Steps

The Massachusetts Medical Society appreciates the opportunity to comment on Medicare Shared Savings ACOs. To be successful, we believe the proposed rule must allow enough flexibility and incentives for physicians, patients and other groups to test voluntarily a variety of new models in a plurality of settings with varied and diverse populations. There are many outstanding and critical issues – inherent to the concept of an ACO – which are yet to be resolved. How do we achieve the projected savings from a risk-based system while allowing a patient’s total freedom of choice without any financial responsibility? And yet, as physicians, we staunchly defend our patient’s right to choose his or her doctor and care setting. At a minimum, CMS should take into account up front the financial implications for patients’ freedom of choice, whether in the form of additional financial resources or in how savings formulas are derived. Should primary care providers be allowed to participate in more than one ACO? A compelling case can be made that they should be. Limiting primary care physicians to only one ACO could discourage primary care physicians from participating and reduce the number of ACOs that can form in a particular community. Given primary care shortages, 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. If a patient has a relationship with a physician, and wants to continue with that physician shouldn’t the patient be allowed to opt out of an ACO and maintain the relationship with their doctor? And perhaps one of the most difficult issues of all, how is CMS going to develop a true risk adjustment measurement to make sure the chronically ill, high-cost patient or patients with health disparities are not abandoned in these systems of care? The science and the metrics do not exist to do this now.

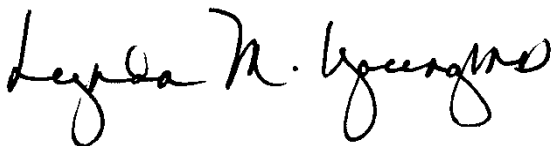
The implications of these issues are magnified when you expand the Medicare Shared Savings ACOs concepts to Medicaid beneficiaries and the pediatric populations. Although the Medicare Shared Savings ACOs are currently focused on Medicare patients; we know there will be implications ultimately for other patients and payers. These issues have been raised at the state level in our conversations. (See Appendix 1 Massachusetts Chapter of the American Academy of Pediatrics on Payment Reform and Child Health.)

We are also keenly aware that a number of other rulemakings are in process regarding changes to current antitrust laws, waivers to federal program integrity rules and provisions to address implications for the tax exempt status of ACOs. The MMS agrees with the AMA that the revisions to the Antitrust Trust laws, Stark and other rules governing program integrity are critical to enable ACOs and new delivery system reforms to succeed. We also join them in urging CMS to ensure that ACOs are permitted to distribute the ACO's savings with physicians and other providers or stakeholders who participate in ACOs without risking their tax exempt status. We refer CMS to the AMA's detailed comments on each of these issues.

The MMS supports the AMA recommendation that CMS issue an interim final rule, as opposed to a final rule, as the next step in the regulatory process. We believe this will allow CMS the flexibility to modify and improve the ACO regulations as the agency learns more about these models.

We look forward to working with you throughout this process.

Sincerely,

A handwritten signature in black ink, reading "Lynda M. Young". The signature is fluid and cursive, with the first name "Lynda" being more prominent than the last name "Young".

Lynda M. Young, M.D., FAAP
President