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Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services

Submitted via e-mail to www.regulations.gov

Re: CMS-1345-P Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations. Document ID: CMS-2010-0259-0425

Dear Dr. Berwick:

The Medical Society of New Jersey is a non-profit physician membership organization. It is the largest physician organization in the state. Most of our 8,000 members practice solo or in a small medical practice.

MSNJ filed comments on December 3, 2010 in response to CMS's request for information on how it might avoid barriers to small practice participation in ACOs. We were disappointed that *not one of our suggestions* was incorporated into this proposed rulemaking. For example, MSNJ requested that the Federal Government fund education/outreach and provide expertise on a variety of issues including risk analysis of financial capacity and infrastructure, and clinical integration. There is an absolute need for either this type of support or for per/member per/month care management dollars up-front to help fund infrastructure and staffing at the primary care practice level. Without some measure of up-front assistance, most small practices will be unable to make the significant practice changes necessary to participate.

We are heartened that CMS's Center for Innovation is proposing a pilot model that would permit advances on savings through the Advance Payment Initiative program. We suggested such an approach in our December 3 comments. This is essential for small practice participation in ACOs. We strongly urge CMS to incorporate an advance payment structure into this proposal from which practices may offset their significant start-up costs.

MSNJ's primary concern with the proposed ACO rules is their immediate shift of financial risk to physicians, especially those in small practices, who wish to participate. The underlying purpose of the ACO regulations and; indeed, the statutory authority for ACOs was to encourage quality and coordination of care in order to achieve savings. The

savings were then to be shared equally between the Federal Government and the ACO participants. Instead, the proposed rules require significant infrastructure and staff investments and then *penalize* ACOs, through cost sharing, if they are unable to achieve the cost savings in year three of the program. If CMS is committed to the possibility of small practice participation in ACOs, then it must create more opportunity for physicians in small medical practices and remove the downside financial risk for their participation.

MSNJ believes that a more accessible ACO program, wider physician community experience, and buy-in would then provide a roadmap for a more stable, sustainable Medicare payment system. Instead, the proposal sets forth a complicated, risk laden program that can only be considered by those with: access to capital; technology already in place and tracked to achieve meaningful use; significant prior experience in coordinated care; knowledge of risk assessment; and the ability to conduct a risk assessment on a retrospectively assigned patient population. There should be a path *with no downside payment risk* for those who wish to participate. All ACO applicants will have significant financial costs associated with the application and start-up. This is sufficient risk-taking without the added risk of payment decreases.

Small medical practices are simply ill-equipped to make these risk assessments and participate in the program as proposed. It is axiomatic that the Medicare program needs more physicians than currently participate in the program to meet the future needs of our aging population. The proposal does nothing to bring physicians in small practices off the side-lines to participate in the process of payment reform and, thereby, improve access to care and keep the Medicare program sustainable. MSNJ is eager to assist our members with payment reform initiatives, but this proposal provides no support for organized medicine to do so. Instead, it is fraught with risks that our rank-and-file members simply cannot assume. Therefore, we suggest that CMS carve out a stream-lined, risk-reduced ACO model for small practices.

CMS Should Remove Small Practice Participation Barriers, or, Create a Solo/Small Practice ACO Model.

To allow meaningful participation by the class of physicians who constitute the majority of physicians in the country--those who are solo or part of a small medical practice--CMS should remove the financial risk of loss sharing in year three of Track One. We believe that this is consistent with the underlying statutory authority—that the program be based on shared savings, not shared losses. Once the downside risk of financial loss in year three is removed, a number of the proposal's onerous requirements would no longer be necessary.

MSNJ suggests that CMS consider the following changes to remove barriers for solo and small practices:

- Remove the financial risk of cost sharing from year three of Track One;
- Remove the financial assurance obligations, as they will no longer be necessary;

- Remove the savings withholding provision, as it will no longer be necessary; and, instead allow for advanced payments on savings;
- Reduce the quality reporting requirements and/or have one set of requirements for the three year commitment period;
- Minimize the technology requirements, including the requirement to effectively achieve meaningful use in year two;
- Emphasize coordination of care;
- Establish performance requirements for the three year commitment at year one;
- Omit the 2% net savings threshold for the Federal Government, thereby allowing first dollar savings; and
- Provide resources to facilitate success, including guidance on risk assessment, and savings projection analysis, among other things.

Alternatively, if CMS is unwilling to make the above changes to the proposal, at large, we urge it to make these changes for a special, small practice ACO model. ***This special model should be available when the majority of the ACO participants are in small practices.*** The essential change from the proposal would be the removal of financial risk of loss sharing in year three of Track One.

In addition to our respectful request that CMS incorporate the above suggestions into the proposal and/or establish a small practice ACO model, we have the following general comments about the proposal.

Track One: Remove Risk of Loss from Year Three

Track One should not include risk-sharing in year three. First, there is no statutory authority for cost-sharing. Second, practices will have to make significant capital expenditures in infrastructure and staff to be able to participate. ***That capital expenditure is a financial risk which should be sufficient for small practices who wish to participate in a Track One ACO.*** Finally, cost sharing in year three is a significant deterrent to participation. Track Two is available for facilities and practices that have already engaged in coordination of care and risk sharing payment models. ***Track One should be a springboard for those with less experience in care coordination and risk-sharing payment models to prepare for Track Two.***

Year One and the Annual Updates Have Baked-In Biases

The proposed methodology for benchmark savings will penalize states, like New Jersey, where there is a high cost of care and an already insufficient Medicare payment rate. The cost of treating Medicare patients in New Jersey is already being subsidized by other patient populations. The current Medicare reimbursement formula, as implemented, underestimates the costs of practicing in New Jersey. The primary reason is that the GPCI formula has a floor that advantages rural areas and disadvantages the entire state of New

Jersey. This under-payment is a baked-in bias that will only be perpetuated with the proposal's benchmark methodology.

To add insult to injury, annual updates based on a ***national average*** are not fair and may not be achievable. We appreciate CMS's effort to balance the tension between low and high cost areas of the country, but the proposal disfavors high cost areas. It starts with the local experience (already skewed against high cost areas) then magnifies the problem by adjusting annually on a **national** flat dollar Medicare growth target. There is no reason to believe that high cost areas will be able to achieve a national growth target as easily as low cost areas.

MSNJ believes that the participants in an ACO program should have a reasonable opportunity for success. We are concerned that the benchmarks may not provide an adequate opportunity for shared savings.

Outliers Must be Better Defined & Excluded

MSNJ has serious concerns that outliers are not adequately defined and that performance benchmarks could easily be missed because of a single case or circumstance that is entirely outside of the control of the ACO. It would be patently unfair to penalize an ACO, through loss sharing, where its best efforts could not result in meeting a benchmark. For example, the New Jersey courts have ordered a hospital to render medically futile treatment over more than a year of intensive care. These costs were astronomical and would not have been incurred, but for the requests of the patient's family and the order of the court. Clearly, costs in this magnitude might cause an ACO not to meet a benchmark. The proposal should allow costs like this to be excluded from the benchmark or, at the very least, not the cause for loss sharing or a termination of the ACO agreement.

Another example would involve an act of God in the vicinity of the ACO (e.g. New Orleans in the wake of Katrina; Joplin, Missouri after the recent tornado). Under the proposed model, ACOs in an area of intensive medical needs, entirely outside of its control, might perform perfectly in years one and two, yet "underperform" in year three and not be entitled to prior savings. A methodology to filter out medical services that are entirely out of the control of the ACO should be considered. In addition, ACOs in such situations should not be subject to termination unless it is mutually agreed to be in the best interest of the ACO.

In addition to the exception for circumstances entirely outside of the control of the ACO, we have serious concerns that the proposed methodology for eliminating outliers is not sufficient and will result in ACOs not achieving the savings benchmarks.

Eliminate the Proposal's 2% Savings Threshold

Under the proposed rules, ACOs would have to achieve a 2% net savings before the remainder of the savings is shared equally between the ACO and the Federal Government. MSNJ sees no reason for the threshold savings requirement. While the 2% threshold is said

by CMS to account for random variation, and may not be attributed to better performance, all ACO participants will be required to make significant capital and staff investments to start-up an ACO. Indeed, there is actuarial data that indicates that the Government has sorely underestimated start-up costs. (CMS estimates that the average up-front cost of an ACO will be \$1.7 million, but the American Hospital Association estimates the cost to be more than \$11 million.) One way to compensate for extraordinary start-up costs would be to eliminate the 2% threshold savings requirement. In fact, this would appear to be a bargain for the Federal Government and Medicare beneficiaries if start-up costs have been significantly underestimated.

Account for the Defensive Practice of Medicine

New Jersey is one of the most litigious states in the country. It is well known that physicians practice defensive medicine which results in greater costs in states where litigation is a reasonable likelihood when there is a bad medical result. Without effective tort reform, or some mechanism to provide reasonable protection to those operating in an ACO, it is unlikely that ACOs in New Jersey or highly litigious states will be able to achieve savings, even with improved coordination of care. No matter how unnecessary, there will be the patient who insists on the latest technology or another test and the ACO must weigh the costs of defending a frivolous lawsuit against the potential savings. Until the defensive medicine factor can be neutralized, the reality of savings is reduced. While difficult to measure, some accommodation should be crafted. For example, if the ACO counsels against a test as unnecessary, yet the patient insists and the results are negative, the ACO should not be penalized where best efforts were made to avoid a test that was not evidence-based. We appreciate that this is a difficult assessment, but coupled with the defective performance benchmark methodology, practices in litigious states will be hard pressed to achieve savings.

Patient Attribution

MSNJ has serious concerns about the retrospective attribution of patients to an ACO. We strongly support a prospective, voluntary assignment process rather than the proposed retrospective claims-driven process. Retrospective attribution is troublesome and presents unique challenges since neither the patient nor the physician knows that CMS is assigning accountability until after the care has been delivered. This makes CMS the decision-maker on physician-patient relationships when patients are best served by making those decisions for themselves. Strong physician-patient relationships will be essential for a successful ACO. A precursor for such a relationship is the patient's voluntary choice.

MSNJ is concerned that the retrospective attribution model facilitates a savings methodology more than it facilitates coordination of care. It is possible that families may end up receiving care from more than one ACO. This, alone, could be disruptive to care since older family members may wish to see the same physicians and benefit from the

informal communication that may occur during another family member's visit. Moreover, retroactively assigned patients have no obligation or incentive to cooperate in the ACO's goal to control expenditures.

Many New Jersey seniors spend a significant period of time out of state, either during the winter (snowbirds) or in summer homes in other parts of the country. Even with best efforts on a continuity of care plan, many of these seniors will require medical care outside of the ACO while they reside elsewhere. The ACO will not have sufficient control over those costs, even with coordination of care. This issue should be addressed either during patient attribution (if the patient is not eliminated based on plurality of services) or adjustments made for services received while living out of state (discounting excessive costs incurred that are outside of the ACOs control). We accept that patients will require care while traveling, or on vacation, and that is a reasonable risk for an ACO to bear, but we question whether individuals with secondary residences are appropriate for ACO assignment or payment decisions.

Primary Care Physician Exclusivity

Under the proposal, primary care physicians are limited to participation in a single ACO for a period of three years. This limitation could discourage primary care physicians from participating and may reduce the number of ACOs that may be formed in certain communities. Family physicians and other primary care physicians often provide healthcare services to many Medicare patients across a broad geographic area and may receive care in multiple tertiary centers and hospitals. By limiting ACO participation to only one Medicare ACO, CMS is essentially limiting ACO participation to only a portion of the primary care practice's Medicare patient population. MSNJ urges CMS to allow primary care providers to participate in more than one ACO.

ACO Application Issues

The proposal requires a demonstration of how the ACO applicant will *utilize savings* to further the ends of the ACO. This requirement is both unreasonable and unrealistic. Small practices are not in a position to "use the savings" to accomplish the goals of the ACO. Many of the start-up costs will be paid before the actual operation of the ACO. Many small practices will be unable to participate on this basis alone because they will not have access to the capital necessary to do so. We anticipate that in many cases savings would be used to pay off loans for start-up costs, and not available to add back into the operation of the ACO.

The proposal also requires a demonstration of how the ACO applicant will *honor patient preferences and cultural differences*. MSNJ agrees that this is consistent with good patient care. Our members will always be guided by these principles. However, there may be an inherent tension in this requirement and the goal of cost savings. For example, it is costly to pay interpreters for their services yet all of this expense is shouldered by

providers.¹ Clearly, coordinated care may provide opportunities for cost-sharing on such services and we believe that ACOs will work to take advantage of shared resources, but this is an expense that is ***totally uncompensated*** under the current Medicare program so all expenses in this regard are a direct out of pocket cost to physicians.

Quality Measures

MSNJ, AMA, and organized medicine requested in the pre-proposal comments that quality reporting measures be limited to those already in place such as the PQRS. We are disappointed that CMS chose extensive quality reporting which is only settled for the first year of a three year commitment. Many practices will be deterred from participating because of the extensive reporting requirements and the uncertainty of additional requirements in years two and three.

Technology Barriers

MSNJ requested that the implementation status of electronic health records (EHR) not be a barrier to participation in an ACO. This proposal requires ACOs to effectively achieve meaningful use by year two of the three year commitment. Given that the vast majority of practices in the country have not successfully implemented EHR, we request that special consideration be given to small practices' ability to participate without achieving meaningful use in the near term. In this regard, we note that the meaningful use criteria is, itself, in flux. We appreciate that achieving meaningful use may be desirable, however, it may not be feasible for the majority of small practices in the near term. Achieving meaningful use should not be a basis for termination from an ACO so long as a practice can coordinate care and meet adopted quality reporting requirements. CMS should give more consideration to the use of registries for quality reporting as this would facilitate more participation by small practices.

Appeal Rights

Generally, MSNJ believes that appeal rights should increase as the ACO matures. Once start-up costs have been incurred, practice changes made, and months of coordinated

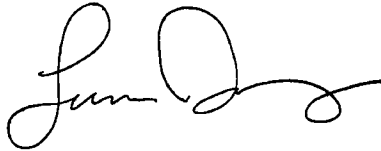
¹ Another example of the tension in New Jersey is the high cost of end of life care. It is well-known that New Jersey has the highest cost of care for end of life medical services. MSNJ has a long term commitment to educating physicians on hospice and palliative care as well as to educating patients about end of life decision-making. These efforts will continue and we expect that any ACO in New Jersey will be compelled to address the high cost of end of life care, especially if they will be measured against a national flat cost update for savings. Nevertheless, to respect patients' wishes and until there is an attitudinal sea-change, in the near term, it is unlikely that the cost curve will be bent on end of life care.

care accomplished, practices have a vested interest in receiving the shared savings for which they qualify. We encourage CMS to ensure impartial, independent review of terminations decisions and the savings calculations. Otherwise, the program will lack credibility and even fewer physicians will be willing to assume the risks of participating in an ACO.

CONCLUSION

We appreciate the opportunity to comment on the proposed rules governing ACOs. We encourage CMS to make a direct investment in the change needed to make the Medicare program sustainable and not simply shift the cost of coordinated care to physicians who are already providing many elements of care for which they are not being compensated. We urge CMS to remove small practice participation barriers or to create a special, streamlined ACO model with no payment reduction risk to permit more participation by small practices. ***Small practices are the backbone of the nation's Medicare healthcare delivery system. A proposal that effectively eliminates them from participating in the payment reform process is a missed opportunity for meaningful payment reform.***

Respectfully submitted,



Lawrence Downs
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On behalf of the Medical Society of New Jersey