

June 6, 2011

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Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: Proposed Rule for the Medicare Shared Savings Program: Accountable Care Organizations;
76 Federal Register 19528 (April 7, 2011) [CMS-1345-P]

Dear Dr. Berwick:

I appreciate the opportunity to submit comments on the Proposed Rule for the Medicare Shared Savings Program and to respond to a number of the specific issues that were raised in the Preamble to the rule.

Summary of Comments

CMS could significantly improve the success of the Shared Savings Program by making the following changes in the Proposed Rule:

1. CMS should revisit each of the requirements of Tracks 1 and 2 and restructure them in a way that would define a more equal partnership with CMS and encourage ACOs to participate. In particular:
 - Reduce the statistical confidence level used to define the minimum savings thresholds, or allow a smaller share of savings if the amount of savings achieves a lower level of statistical confidence.
 - Allow all ACOs that achieve minimum savings thresholds to share in the first dollar of savings.
 - Either define up front what the quality performance standards will be throughout the three-year term of the agreement, or guarantee a minimum share of savings regardless of what the ACO's quality scores are.
 - Eliminate the 25% withhold provision.
 - Compute an ACO's shared savings payment using 6 month rather than annual performance periods, use a 3 month claims lag to estimate total costs, and issue shared savings checks within 30 days after the amount of the shared savings payment has been determined, with no requirement for invoicing by the ACO.

- Eliminate the cap on the total amount of savings that can be shared.
- 2. In addition to making all of the changes described above, CMS should authorize ACOs under Track 2 to be paid immediately for key services that are not currently reimbursable under Medicare, e.g., phone calls and email communications between patients and physicians, use of nurse care managers to provide education and self-management support for patients with chronic disease, etc.
- 3. CMS should offer Accountable Care Organizations the option of being paid under a partial capitation payment model, as authorized by the Affordable Care Act. To the extent that making the capitation payment “partial” creates administrative challenges for CMS, particularly in the short run, it should offer whatever version of such a model that it can implement quickly, and let potential ACOs decide whether they can participate.
- 4. CMS should create an Accountable Medical Home program that would pay primary care practices in ways that enable them to take accountability for reducing non-urgent emergency room visits, ambulatory care sensitive admissions, and duplicative and unnecessary testing.
- 5. CMS should modify the regulations under the Shared Savings Program so that ACOs would only be accountable for the costs of services to beneficiaries who elect participation in the ACO, and only for costs incurred for those beneficiaries after they join the ACO.
- 6. CMS must include a method of adjusting the calculation of shared savings to account for changes in the number and severity of ACOs’ patients’ health conditions.
- 7. CMS should allow ACOs to report on and be held accountable for quality measures that are being collected and publicly reported by a Regional Health Improvement Collaborative in their community, in place of some of the measures proposed by CMS.
- 8. CMS should require that, in order to participate in the Medicare Shared Savings Program, all large provider organizations would need to go through the same type of review process as would collaborations of independent providers.
- 9. CMS should only include requirements regarding the structure or internal systems of ACOs where there is clear evidence that high-quality, affordable care *cannot* be provided without such structures or systems.
- 10. CMS should authorize more extensive waivers of the fraud and abuse statutes for ACOs, with a particular focus on allowing ACOs to replicate changes that have been successfully implemented in demonstrations where such waivers have been allowed.

The rationale for these recommendations and more detail on how they should be implemented are provided below.

Create a True Partnership Between CMS and ACOs in Tracks 1 and 2

You have indicated publicly that CMS is seeking to be a “trustworthy partner” with healthcare providers, and this is a laudable and welcome goal. However, unfortunately, the proposed regulations are clearly structured in a way that makes CMS the “senior partner” in terms of financial benefit, even though the ACO will be the entity doing all the work and contributing all of the capital.

Ordinarily, partners in a joint venture each contribute capital to that venture. It is widely agreed that, in order to achieve success, most ACOs will need to incur significant costs – not only in terms of actual cash outlays but also losses of revenue from fewer reimbursable services. Yet CMS is not providing any upfront capital to help ACOs cover those costs. Shared savings payments may or may not cover these costs, since the rules for sharing savings are being pre-defined in the regulations with no flexibility to adapt to the actual nature and timing of the investments needed. Even if the shared savings payments would cover the upfront investments, they will come well in the future, and the 3-year agreement with CMS may not be long enough to recoup all of them.

It is also generally desirable that partners in a joint venture contribute effort to making the venture a success. In some cases, one partner will contribute more of the capital needed and another will contribute more of the actual operational work. However, under the Shared Savings Program, all of the effort to change the way care is being delivered is also coming from the ACO. For example, despite the importance of having Medicare beneficiaries educated and engaged in ways to improve the coordination of their care, CMS has not committed to any specific plans for how it will support that type of education and patient engagement.

Good partners define their mutual obligations in writing at the beginning of their partnership, and while they can negotiate changes in the future if needed, they cannot change those obligations unilaterally. Yet under the proposed rules, CMS states that it can and likely will change many of the rules midstream and that ACOs will be required to abide by those changes, regardless of how unfavorable they may be.

Partners in a joint venture typically expect to receive returns and share losses in some fashion that is proportional to their investments and effort in making the venture a success. Yet despite the fact that the ACOs will be making all of the upfront investment and contributing all or most of the effort in changing the way care is being delivered, the regulations favor CMS financially at every turn. There are at least six different ways that CMS can delay or reduce payments to ACOs under the regulations:

- Even if savings are achieved, if the savings are too small to convince CMS that the savings are not “random,” the ACO will get no share of the savings that are achieved, and CMS will keep the entire amount. The thresholds for proving that savings are not random are very high for small ACOs because CMS is demanding a high level of statistical confidence. Failure to achieve the thresholds would not mean that savings weren’t achieved – indeed, expenditures could be lower than expected by nearly 4% – merely that, according to CMS calculations, the probability that the savings were not random was less than 95%.
- Except for the smallest ACOs, if the minimum savings defined by CMS are achieved, CMS will keep every dollar of savings up to 2% of projected costs before any portion is shared with the ACO. This could easily mean that ACOs will receive no shared savings payments or a very small payment, even though CMS will be saving a considerable amount. It is important to recognize that if the changes in care the ACO has made in order to generate savings are made for all of its patients, it will likely be incurring losses across multiple payers, not just Medicare, and so CMS’s failure to share the first dollar of savings with the ACO will magnify the ACO’s financial problems.

- Even if the ACO is eligible to share in savings under CMS's rules, the amount that it can receive will be reduced or even eliminated if the ACO fails to meet quality performance standards which have yet to be defined and may be unattainable. It could well be that an ACO would maintain or improve its current levels of quality and reduce costs, yet receive no shared savings payment because its quality scores failed to meet whatever standard CMS chooses to define.
- If it turns out that the ACO is eligible for a shared savings payment, CMS will withhold 25% of the amount as a reserve against potential future losses.
- After all of this, if the ACO should manage to qualify for some shared savings payment, CMS will not make a determination of what that payment is until an unspecified time at least 6 months after the end of the performance period.
- Finally, once CMS makes the determination of the shared savings payment that the ACO is eligible for, it will not actually send the check; the ACO will be required to verify CMS's calculation, send an invoice, and then wait for an unspecified time to receive payment. (In contrast, if CMS determines that there have been losses, the ACO is required to send CMS a check within 30 days.)

On top of all of this, the maximum share of savings that an ACO can receive under Track 1 is 50% (52.5% if a large proportion of patients have visits to a Federally Qualified Health Center), even if the ACO has incurred costs or losses greater than that in order to achieve the savings for Medicare. The effective percentage will be lower if the actual savings are very large, because if savings exceed 15%, CMS would retain 100% of the savings beyond 15%. This actually penalizes the most successful ACOs, since the more savings they generate for Medicare beyond the maximum, the smaller the share of their lost revenue they will recoup.

The 25% withhold also penalizes the most successful ACOs, since the withhold amount would be higher for ACOs that achieve greater savings, even though ACOs that achieve higher savings in the first two years would be the least likely to have expenditures exceed projections in the third year, which is the sole reason for having the withhold. In contrast, ACOs which generate no savings during the first two years would be the most likely to have expenditures exceed projections in the third year, but nothing would be withheld from those ACOs because there would be nothing to withhold.

Finally, partners in innovative business arrangements generally recognize that it will take time – often many years – to be successful and that there will likely be setbacks along the way. But under the proposed rules, CMS would give a very short amount of time – 3 years – for an ACO to reinvent care processes that have formed over several decades, and CMS could suspend payments or terminate the ACO arrangement early if the ACO fails to meet all of the requirements CMS has imposed, even if those requirements turn out to be difficult or impossible to meet.

Clearly, despite the fact that CMS desperately needs ACOs to help it achieve savings in the Medicare program, almost every aspect of the proposed rules is structured in a way designed to discourage providers from forming such ACOs. In trying to maximize the benefit for the Medicare Trust Fund from the Shared Savings Program, CMS could well eliminate the opportunity for any benefit at all.

CMS should revisit each of the requirements of Tracks 1 and 2 and restructure them in a way that would define a more equal partnership with CMS and encourage ACOs to participate. In particular:

- Reduce the statistical confidence level used to define the minimum savings thresholds, or allow a smaller share of savings if the amount of savings achieves a lower level of statistical confidence. This will make it more likely that smaller ACOs can succeed.
- Allow all ACOs that achieve minimum savings thresholds to share in the first dollar of savings. This will make it more likely that ACOs can recoup the costs and losses they have incurred in generating savings for CMS.
- Either define up front what the quality performance standards will be throughout the three-year term of the agreement, or guarantee a minimum share of savings regardless of what the ACO's quality scores are. This will enable the ACO to more accurately determine what amount of shared savings it will receive before it makes investments or incurs losses.
- Eliminate the 25% withhold provision. This only penalizes successful ACOs, and does nothing to ensure that unsuccessful ACOs share in CMS's losses.
- Compute an ACO's shared savings payment using 6 month rather than annual performance periods, use a 3 month claims lag to estimate total costs, and issue shared savings checks within 30 days after the amount of the shared savings payment has been determined, with no requirement for invoicing by the ACO. This will help ACOs more quickly recoup costs and losses they incur.
- Eliminate the cap on the total amount of savings that can be shared.

Additional changes that could be made to deal with the upfront costs and losses that ACOs will likely occur are addressed below.

Fix Weaknesses of the Fee for Service System Under “Track 2”

Rather than implementing the pure “shared savings” model specified in law, CMS chose to use its authority under Section 1899(i) of the Affordable Care Act to design two different payment models that it believed would be more effective. Although CMS is to be commended for recognizing that the pure shared savings model has many weaknesses and for attempting to design something better, it failed to take full advantage of the flexibility in Section 1899(i) to create at least one payment model that actually changes the underlying fee for service system. Even the so-called “two-sided risk” model in the Proposed Rule is nothing more than a pay-for-performance add-on to the existing fee-for-service system. Under both Tracks 1 and Track 2, the providers in the ACO continue to get paid exactly as they do today in each of the performance years, and so changing how they deliver care can harm them financially, even if the change is better for patients and saves Medicare money. For example, physicians will still get paid only for things on the Medicare fee schedule, and they will lose revenue if they do something for a patient that isn't on the schedule in place of something that is (e.g., if they address a patient's problems over the phone or by email, rather than forcing the patient to come into the office); hospitals will still get paid for procedures at the DRG rates, and their revenues will decline more than their costs if they find ways to help patients avoid procedures or use lower-cost procedures. Physicians and hospitals in the ACO may recoup some of these losses through shared savings

payments, but as described earlier, they will not know for certain whether this will happen or how much they will receive, and even if there is a payment, it will certainly not be timely.

In addition to making all of the changes described previously, CMS should authorize ACOs under Track 2 to be paid immediately for key services that are not currently reimbursed under Medicare, e.g., phone calls and email communications between patients and physicians, use of nurse care managers to provide education and self-management support for patients with chronic disease, etc. Many of these services have CPT codes and have RVUs assigned to them, but they are not currently authorized for payment by Medicare.

There is considerable evidence that these kinds of services will save considerable amounts of money for Medicare – for example, many projects have shown that hospital admission and readmission rates for chronic disease patients can be reduced dramatically simply by having nurse care managers providing better patient education and self-management support and/or by encouraging patients to call their physician immediately upon the first signs of an exacerbation of their disease. Nonetheless, CMS may be concerned that an ACO will bill for these services but not use them in a way that reduces utilization elsewhere, and the ACO will thereby increase total expenditures for Medicare. However, this should be less of a concern under Track 2 because the ACO would be responsible for paying CMS back if total expenditures increase rather than decrease. If CMS is concerned that the increase in expenditures might fall below the threshold for sharing losses, CMS could require ACOs to share in the first dollar of losses if the ACO wishes to receive payment for the currently unreimbursable services.

Create a Truly Different and Better “Track 3”

Even if CMS improves the methodology for determining and paying shared savings and authorizes payment for additional high-value services, ACOs would still be paid primarily under the existing fee-for-service system, a system that is widely recognized as discouraging the delivery of high-value care.

Section 1899(i) of the Affordable Care Act gives CMS the power to create completely different payment models that would correct the problems with fee-for-service in much more fundamental ways than any shared savings model can. There are a number of physician groups and health systems around the country that are ready to take on such models and deliver even better care for patients and greater savings for CMS than they could under any type of shared savings model. Consequently, CMS should create one or more “Track 3” payment models that enable these providers to do what they can and want to do.

In particular, CMS should offer Accountable Care Organizations the option of being paid under a partial capitation payment model, as is explicitly authorized in the Affordable Care Act. Under this payment model, an ACO would agree to accept a pre-defined monthly per-patient payment during a multi-year period that would be used to cover all of the costs of care for a defined group of patients. The payment would be lower than what CMS would project paying for those patients under the current fee-for-service system, thereby guaranteeing savings for Medicare. This model would enable physician practices with experience in successfully managing capitation contracts under Medicare Advantage and commercial insurance to deliver better care to Medicare fee-for-service beneficiaries as well as provide guaranteed savings to the Medicare program. A more detailed description of how this model could be implemented and its

advantages compared to shared savings is available at the Center for Healthcare Quality and Payment Reform's website (<http://www.chqpr.org/downloads/PartialCapitationPaymentforACO.pdf>), and CMS should use it as a framework for implementing Section 1899(i)(1) of the Affordable Care Act.

CMS should also provide Accountable Care Organizations with the option of using a “virtual partial capitation” payment model. Under this payment model, CMS would define a per-patient budget for a defined group of patients instead of making an upfront payment to the ACO; individual providers would bill for individual services, the total billings would be compared to the budget, and the payments to the providers in the ACO would be adjusted up or down to keep the total payments within the budget. This is also described in more detail in the document referenced previously.

To the extent that making the capitation payment “partial” creates administrative challenges for CMS, particularly in the short run, CMS should offer whatever version of such a model that it can implement quickly, and let potential ACOs decide whether they can participate.

Create Transitional Payment Models to Help Providers Become ACOs

Although the most sophisticated and experienced providers will likely be able to achieve far better results under partial capitation than under the shared savings model, there are many providers who are not able or willing to enter into a partial capitation arrangement under the Medicare fee-for-service program, at least not yet. It would be desirable to give smaller and less experienced providers an opportunity to deliver the kinds of improvements in care and reductions in cost that they are able to, but which the current payment system precludes. Although the shared savings program has been described as an “on ramp” for less experienced providers, it is actually a very steep on-ramp, and even if the improvements suggested earlier are adopted, many such providers will still be unable to participate.

Consequently, CMS should offer transitional payment models for such providers, either under the Shared Savings Program, the Innovation Center, or both. In particular, as part of the Shared Savings Program, CMS should create an Accountable Medical Home program that would pay primary care practices in ways that enable them to take accountability for reducing non-urgent emergency room visits, ambulatory care sensitive admissions, and duplicative and unnecessary testing. This would work as follows:

- **Component 1: Care Management Payment.** The primary care practice would continue to be paid at current fee levels for each individual service the practice delivers to any patient it sees, but in addition, a new Care Management Payment would be added to pay the practice for care management services (e.g., patient education and self-management support delivered by a physician or nurse, access to physicians by telephone, etc.) to a group of patients (either all of the primary care practice's Medicare patients or a subset of those patients, such as those who have specific diseases). The payment would be made on a per-patient basis, i.e., the practice would receive the payment regardless of what specific services it provides, or how many services are provided to any individual patient.
- **Component 2: Targets for Utilization Reduction.** The physician practice would also agree to improve the way care is delivered to its patients so that the rates of utilization of specific healthcare services outside of the practice (e.g., non-urgent emergency room

visits, ambulatory care sensitive hospitalizations, or high-tech diagnostic imaging) are below specific target levels. The target levels would be lower than current utilization rates, such that the reduction in utilization, multiplied by the amounts Medicare pays for the services being reduced, would result in aggregate savings for Medicare that are greater than the aggregate amount of payment made under Component 1.

- **Component 3: Bonuses/Penalties for Performance Against Targets.** A third component would be a pay-for-performance type of payment that would reward the practice for doing better than the targets and penalize it for failing to achieve the targets. The physician practice could receive a fixed bonus or “shared savings” payment for reducing utilization below the target level, but it would be required to refund all or a portion of the upfront care management payment to Medicare if it failed to achieve the target level (with the amount of the refund being proportional to how far above the target the actual utilization for the patients was).

For example, suppose a multi-physician primary care practice manages a total of 5,000 Medicare patients who collectively make an average of 450 visits to emergency rooms each year for non-urgent reasons, at an average cost to Medicare of \$1000 per visit. If the practice became an “Accountable Medical Home” Medicare would pay the practice a monthly Care Management Payment of, say, \$2.00 for each patient to enable the practice to improve access for patients (e.g., longer office hours, weekend hours, and improved phone support). This would represent \$120,000 in additional annual revenues to the practice. The practice would agree that in return for the Care Management Payment, it will take accountability for reducing the rate of non-urgent ER visits by 30%. If it succeeds in doing this, Medicare will save more on ER visits ($\$135,000 = 30\% \times 450 \times \1000) than the cost of the Care Management Payments. If the practice reduces non-urgent ER visits by more than 30%, the practice would receive a bonus payment from Medicare equal to one-half of the cost of the additional prevented ER visits, but if it fails to meet the 30% target reduction, it would be required to pay Medicare back for the portion of the Care Management Payment equivalent to the cost of the extra ER visits.

A payment system with the above three components would be preferable to the current fee-for-service system, where the primary care practice receives no resources to help reduce emergency room visits, hospitalizations, etc., receives no financial penalty if they remain constant or increase, and receives no reward if ER visits or hospitalizations are reduced. But it would also be easier for a small practice to participate in than the proposed Medicare Shared Savings Program for two reasons: (1) the practice would receive the upfront resources it needed to change the way it delivered care, and (2) the practice would not have to accept accountability for the total costs of care for its patients, particularly aspects of care that it cannot possibly control, even if it can make a major impact on ER utilization.

This approach simulates the flexibility and accountability inherent in a capitation or global payment system, but limits both flexibility and accountability in ways that make it a more practical step for both the primary care practice and Medicare. The Care Management Payment is both flexible and predictable, as a full global payment would be, and the utilization targets and bonuses/penalties give the practice incentives to manage utilization similar to what providers need to do to succeed under global payment arrangements. But under this payment model, the practice would not be placed at risk for increases in the *total* cost of care for these patients, or be expected to reduce the *total* costs of care in order to receive any additional payments from Medicare.

The Care Management Payment in Component 1 is similar to what CMS is already paying a number of primary care practices in the Multi-Payer Advanced Primary Care Demonstration. However, that Demonstration does not require that the medical homes accept any explicit accountability for reducing utilization of other services. Components 2 and 3 address this weakness by directly tying the increased payment to savings elsewhere.

Medicare might understandably be concerned that basing targets and rewards/penalties solely on *specific services*, such as the rate of hospitalizations, rather than on *all services* to the patient runs the risk that the practice will utilize some other expensive services (e.g., increasing referrals to specialists) to reduce hospitalizations, thereby increasing total costs for Medicare. However, if the primary care practice understands that this is a *transitional* payment system, and that targets for additional aspects of utilization will be phased in over time, then it would be undesirable for the practice to significantly increase the utilization of services that are unmeasured this year, only to have a bigger challenge of reducing them next year when those additional services are also being measured. In the meantime, giving the practice an easily understood and measured target to focus on initially would facilitate its ability to move toward more accountable care.

Setting targets based on *utilization of services*, rather than *total cost*, is also important, since it is reasonable to expect that a primary care practice can help manage patients' conditions in ways that avoid ER visits and hospitalizations, but it is not reasonable to expect that PCPs can control what happens once the patient is hospitalized, particularly when the hospital care is being managed by hospitalists or other physicians. Focusing on utilization avoids putting the practice at risk for the cost of hospital-acquired infections or price changes by hospitals or other providers that could wipe out any savings from reduced utilization.

In addition to creating the Accountable Medical Home model, it would be desirable if CMS created other transitional payment models, either under the Shared Savings Program or the Innovation Center. Examples of these other models are described in detail in the Center for Healthcare Quality and Payment Reform's report *Transitioning to Accountable Care: Incremental Payment Reforms to Support Higher Quality, More Affordable Health Care*, available at www.CHQPR.org.

Eliminate the Use of Statistical Attribution During Performance Periods

Any method for "attributing" patients to physicians will inherently result in misclassifications if it attempts to define a relationship between patients and physicians that they have not agreed to themselves. Retrospective attribution is particularly problematic, since neither the patient nor the physician will know that CMS is assigning accountability to the physician for the costs of the patient's care until after the care has already been delivered. Use of retrospective attribution could create an undesirable incentive for ACOs to avoid providing primary care services to new Medicare patients, since a single visit could result in all of the beneficiary's healthcare costs being attributed to the ACO.

Rather than attempting to solve these problems by further modifications to a fundamentally flawed methodology, CMS should modify the regulations under the Shared Savings Program so that ACOs would only be accountable for the costs of services to

beneficiaries who elect participation in the ACO, and only for the costs of services incurred on behalf of those beneficiaries *after* they had joined the ACO.

In the Preamble, CMS states that its goal in using retrospective attribution is to ensure that ACOs treat all of their patients the same. Remarkably, the proposed regulations are intentionally structured to prevent the ACO from knowing who its patients are; the Preamble states that ACOs “will still be encouraged to provide high quality, efficient, and well-coordinated services to all Medicare FFS beneficiaries because they will not know for sure who will be in the assigned population.”

But the goal of creating ACOs is, in fact, precisely to enable ACOs treat their patients *differently*. It is a waste of an ACO’s resources to attempt to provide proactive outreach or care coordination services for a patient who has no desire for such services (perhaps because they only saw the PCP affiliated with the ACO for a second opinion), or if the patient has already decided to seek care through another ACO or non-ACO provider (perhaps because the patient has moved out of the community unbeknownst to the ACO). If CMS wants the ACO to provide better services to *all* of its patients, CMS needs to pay the ACO to do that for *all* of its patients, not just for a subset that meet an arbitrary attribution rule, particularly one that is known to leave one third of Medicare beneficiaries unattributed to any provider.

Moreover, retrospective attribution does not ensure that all patients will be treated the same, particularly because the retrospective attribution model not only attributes the patient to the ACO, but also attributes all of that patient’s costs to the ACO, *including costs that were incurred prior to the patient actually coming to the ACO for care for the first time*. Given the financial penalties associated with having a patient attributed to the ACO who incurred high costs earlier in the year or who does not actively support the ACO’s efforts to coordinate care, an ACO could easily decide to interview prospective patients before accepting them for care the first time. If the ACO determined that a patient had had significant amounts of acute care earlier in the year but no primary care, it might decide not to accept the patient even for a single primary care visit because of the risk that all of the patient’s costs earlier in the year would be attributed to the ACO. Conversely, if the ACO determined that the patient was coming to its providers for a specific procedure, but the patient had received, and would continue to receive, their primary care from a non-ACO provider, the ACO might decide to accept the patient but be much less conservative about testing and treatment knowing that the costs associated with that patient would be attributed to some other ACO or non-ACO provider.

It appears from the Preamble that CMS did not even consider an option to base an ACO’s shared savings calculation solely on beneficiaries who actually select the ACO. CMS described in the Preamble the advantages and disadvantages of prospective versus retrospective *attribution*, but it did not describe what, if any, concerns it has about a model under which beneficiaries would voluntarily “sign up” for the ACO.

An elective participation model would not restrict a beneficiaries’ choice in any way. Indeed, it would actually improve a beneficiary’s choices because under the proposed rule, the only way that a beneficiary can completely opt out of being part of the ACO (as opposed to merely opting out of data sharing) is to switch to a different doctor. Allowing a beneficiary to elect whether to be in the ACO or not would enable them to stay with their doctor (if the doctor is willing to see patients who do not want to be part of the ACO).

An elective participation model would also appear to be administratively feasible for CMS, since the proposed regulations allow beneficiaries to opt out of data sharing with an ACO (which would require CMS to track which beneficiaries are “in” and which are “out”) and since the Pioneer ACO Model announced by the Innovation Center enables beneficiaries to elect participation in an ACO.

CMS should not be concerned that an elective participation model would encourage ACOs to “cherry pick” patients, since, as described above, this is not precluded by the retrospective attribution model, either. Indeed, elective participation would make cherry-picking less likely, since the ACO would not be responsible for costs the patient incurred prior to joining the ACO, only costs incurred afterward, and patients with high needs would represent opportunities to significantly reduce costs through better care coordination (assuming appropriate risk adjustment is included in the payment model, as discussed in the next section).

The definitive criterion should be to choose the approach that best reflects the way the American public ultimately want to see care delivered and paid for, and that is clearly having patients choosing their physicians and having a physician and his or her colleagues taking accountability for the quality and cost of care delivered to the patients who choose them. Using an elective participation model is the best and only way to do that.

Include Risk Adjustment Under All Tracks

Healthcare providers generally have little or no control over whether a patient will have serious or major health conditions such as cancer or trauma. The fact that some patients need more services, and therefore incur higher healthcare costs, because they have more health conditions or more severe conditions is known as “insurance risk.” Conversely, once a patient has a particular set of health conditions, healthcare providers have the ability to control how many and what types of services the patient will receive to treat those conditions, and therefore providers (not Medicare) have the most direct influence on the quality and cost of care for any given combination of conditions.

Consequently, a good payment system to support ACOs will retain as much insurance risk (the risk of whether a patient has an illness or other condition requiring care) as possible with Medicare, and transfer as much “performance risk” (the risk of whether a condition can be treated successfully for a specific amount of money) as possible to ACOs.

The principal method for separating insurance risk and performance risk is the use of a risk adjustment or condition/severity-adjustment system. If one patient has more health conditions or more severe conditions than another, Medicare should expect that, on average, any ACO will spend more to deliver services to that patient than to a healthier patient. In the absence of such a risk adjustment system, an ACO could be financially penalized for caring for sicker patients, and Medicare could award shared savings payments to an ACO simply because that ACO happened to get healthier patients than others.

It is essential that the Shared Savings Rule include a method of adjusting the calculation of shared savings to account for changes in the number and severity of an ACO’s patients’ health conditions. CMS risk adjusts payments to *health insurance companies* in the Medicare Advantage program, yet CMS is proposing *not* to risk adjust the shared savings payment calculations for *providers* who form ACOs. It would be one thing if ACOs were not at risk for

increases in costs; in that case, the lack of risk adjustment would simply be one more way that Medicare would prevent ACOs from receiving shared savings payments. But if CMS wishes to also make ACOs accountable for increases in costs, it must ensure that those increases in costs were due to things that physicians, hospitals, and other healthcare providers in the ACO had some potential to control, and not penalize the providers for the effects of genetics or accidents.

If CMS is concerned that existing risk adjustment methodologies have rewarded health plans or providers for savings inappropriately, then CMS should modify the risk adjustment methodology, not eliminate risk adjustment entirely. For example, to the extent that ACOs are better documenting pre-existing conditions for their patients, those pre-existing conditions could be used to modify the baseline risk scores for those patients, thereby assuring that any increase in a patient's risk score reflects new conditions, not better documentation.

Allow Local Flexibility in Quality Measurement

The major drivers of costs differ from community to community, and so the biggest savings in Medicare costs for CMS will likely be achieved if ACOs in different parts of the country change the aspects of care that are driving costs in their community. Although it is certainly important to ensure that these efforts to reduce costs do not negatively impact the quality of care for patients, CMS will not be able to assure this through any single set of quality measures selected at the national level, since they may bear little relationship to the specific types of patients or types of care on which a particular ACO is focusing its care improvement and cost reduction efforts. In addition, forcing the ACO to try and improve a large number of measures may also force the ACO to divert attention from efforts to reduce costs in areas where there are significant opportunities for cost reduction, thereby reducing savings for CMS and the ability of the ACO to recoup a portion of those savings. The practical reality is that healthcare providers can only implement a limited number of quality measurement and improvement initiatives at one time while still keeping up with patient care responsibilities.

Fortunately, CMS does not need to try and assure the quality of care for Medicare beneficiaries by itself. There are dozens of Regional Health Improvement Collaboratives across the country – non-profit, multi-stakeholder, community-based organizations which are working to improve the quality and reduce the costs of health care in their communities – that currently measure and publicly report on the quality of healthcare services in their communities. Examples include the Albuquerque Coalition for Healthcare Quality (www.abqhealthcarequality.org), Aligning Forces for Quality – South Central Pennsylvania (www.aligning4healthpa.org), Better Health Greater Cleveland (www.betterhealthcleveland.org), the California Cooperative Healthcare Reporting Initiative (www.cchri.org), the Greater Detroit Area Health Council (www.gdahc.org), the Health Improvement Collaborative of Greater Cincinnati (www.the-collaborative.org), Healthy Memphis Common Table (www.healthymemphis.org), HealthInsight (www.healthinsight.org), the Integrated Healthcare Association (www.ihc.org), the Iowa Healthcare Collaborative (www.ihc.org), the Kansas City Quality Improvement Consortium (www.kcqic.org), the Louisiana Health Care Quality Forum (www.lhcqf.org), the Maine Health Management Coalition (www.mehmc.org), Massachusetts Health Quality Partners (www.mhqp.org), the Midwest Health Initiative (www.mhi.org), Minnesota Community Measurement (www.mncommunitymeasurement.org), the Oregon Healthcare Quality Corporation (www.q-corp.org), the Puget Sound Health Alliance

(www.pugetsoundhealthalliance.org), and the Wisconsin Collaborative for Healthcare Quality (www.wchq.org).

Not only are these Regional Health Improvement Collaboratives already collecting and publicly reporting an extensive array of quality measures, they are also actively using them to encourage improvements in the quality of healthcare in their communities. Indeed, in many cases, the measures have been developed specifically to support a local quality improvement initiative, rather than the other way around. This type of synergy between measurement/reporting initiatives and quality improvement initiatives at the local level is precisely what will help Accountable Care Organizations be successful.

Consequently, CMS should allow ACOs to report on and be held accountable for quality measures that are being collected and publicly reported by a Regional Health Improvement Collaborative in their community, in place of some of the measures proposed by CMS. For example, CMS could allow an ACO to substitute locally collected and reported measures for a subset of the default CMS measures in the same measurement domain. CMS could still compare an ACO's quality to other ACOs nationally based on a smaller, minimum set of measures, but it could base shared savings payments on the ACO's performance on a combination of nationally and regionally-defined quality issues, thereby better supporting local quality improvement priorities.

Discourage Anticompetitive Behavior by All Types of ACOs

The proposed rules require that ACOs which have two or more participants providing more than 50% of the same service in a particular geographic area must seek an antitrust review from the Federal Trade Commission and the Department of Justice. A serious weakness with this is that it only affects ACOs created through collaborations of otherwise independent providers. A group of independent physicians or other providers who wish to collaborate in the commercial market would be required to (1) meet CMS requirements in order to qualify for rule of reason treatment, (2) conduct PSA analyses to determine whether they fall into the safe harbor, and (3) submit to expedited antitrust reviews if they do not, but a similar number of physicians who are part of a single practice or who are employed by a hospital would not be required to do any of these things in order to act as a single, jointly priced entity in the commercial market.

This clearly creates burdens and hurdles to the creation of such collaborations that do not apply to single provider entities that are identical in all other relevant respects. In many cases, the practical effect of this will not be to preserve competition by the independent entities that are seeking to collaborate, but to either (a) weaken their ability to compete against larger consolidated entities, by forcing them to drop their plans to collaborate or (b) encourage the independent providers to consolidate into a larger entity (or in the case of physicians, to seek employment with a larger entity) which will not be subject to the requirements at all. In either case, the result would be less competition, not more, which is completely counter to what CMS, the FTC, and DOJ say they are seeking to achieve. (This is analogous to increasing criminal penalties only for robberies with firearms; the effect is as likely to be an increase in the number of robberies with knives and other deadly weapons as it is to reduce the total number of robberies, and research shows that such a shift can actually be more deadly for the robbery victims.)

Limiting the requirements in the regulation just to collaborations of independent providers is implicitly based on two fallacies:

- First, it implicitly assumes that if independent providers are precluded from collaborating, their only choice is to remain independent and compete with each other. But in fact, they also have the choice of consolidating with each other (e.g., through a merger) or joining other organizations (e.g., seeking employment with a hospital).
- Second, it implicitly assumes that precluding a collaboration of small independent providers, but allowing formation of a single consolidated entity with the same number of providers, would be desirable for competition. In fact, it is exactly the opposite: if independent providers collaborate but remain independent, the individual providers have greater ability to later withdraw and form new competitive structures than if they give up their independence and consolidate into a single entity or seek employment with a hospital or other organization.

Although CMS is to be commended for recognizing and trying to prevent potential negative impacts that formation of ACOs could have on prices and costs in the commercial market, the proposed rule could actually exacerbate the problem it is trying to prevent by encouraging greater consolidation of providers.

To solve this, CMS should require that, in order to participate in the Medicare Shared Savings Program, all large provider organizations would need to go through the same type of review process as would collaborations of independent providers. For example, if any ACO with a high market share wishes to participate in the Shared Savings Program, it would need to undergo the same type of review that is required for collaborations of independent providers, and it would be prohibited from participating in the Shared Savings Program if it fails that review.

Remove Barriers to Participation and Success

One of the commendable things about the authorization for the Shared Savings Program in the Affordable Care Act is that it allows a wide variety of types of providers to participate as ACOs, ranging from small physician practices to large health systems. But the Proposed Rule has undercut some of the flexibility in the law by creating structural requirements for ACOs that favor larger and wealthier provider organizations. For example, the proposed rules require that 50% or more of the physicians in the ACO be “meaningful users” of electronic health records (EHRs); while having such systems is *desirable*, there is no evidence that they are *essential* for physician practices to successfully coordinate care and manage costs, but it is quite clear that they are *expensive*. Indeed, there are many examples where physician practices deliver high quality, affordable, coordinated care without such systems, and there is evidence showing that implementation of such systems can have negative impacts on the quality and cost of care during implementation phases. If CMS wants providers to use EHRs, it should pay for them, but not force providers to spend large amounts of money that might be better invested in other areas with equal or greater benefit for patients. In the final regulations, CMS should only include requirements for the structure or internal systems of ACOs where there is clear evidence that high-quality, affordable care *cannot* be provided without such structures or systems.

At the other end of the spectrum, there are a series of barriers that exist today that limit the ability for physicians, hospitals, and other providers to reinvent the way they deliver care and

reallocate resources in new ways. Many of these barriers derive from the “fraud and abuse rules,” i.e., the Stark law, the Anti-Kickback statute, and the Civil Monetary Penalty statute. Although the Affordable Care Act explicitly authorizes the Secretary of Health and Human Services to waive these requirements for ACOs, the only waivers proposed so far apply narrowly to distributions of shared savings payments, if any, and do not allow greater flexibility with respect to the underlying fee for service system that may be necessary to generate savings. For example, various gainsharing projects, including Medicare’s current Acute Care Episode Demonstration, have proven that enabling hospitals and physicians to share savings on specific procedures has enabled significant savings to be achieved. In the final regulations, CMS should authorize more extensive waivers of the fraud and abuse statutes for ACOs, with a particular focus on allowing ACOs to replicate changes that have been successfully implemented in demonstrations where such waivers have been allowed.

I appreciate the opportunity to submit these comments, and I would be happy to provide any additional information regarding them or to assist you in implementing them.

Sincerely,

A handwritten signature in black ink, appearing to read "H. D. Miller". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Harold D. Miller
Executive Director

cc: Jonathan Blum
Richard Gilfillan
John Pilotte
Terri Postma
Elizabeth Richter