MEDPAC Medicare Payment Advisory Commission

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Dr. Donald M. Berwick
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
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Washington, DC 20201

RE: File code CMS-1345-P

Dear Dr. Berwick:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Medicare Shared Savings Program: Accountable Care Organizations proposed rule, published in the April 7, 2011 *Federal Register*, vol. 76, no. 67, pages 19528 to 19654. The proposed rule addresses many of the myriad issues that will need to be resolved to effectively implement accountable care organizations (ACOs) participating in the Medicare shared savings program under section 3022 of the Patient Protection and Affordable Care Act (PPACA). If structured carefully, a shared savings program for ACOs could present an opportunity to correct some of the undesirable incentives inherent in fee-for-service payment and reward providers who are doing their part to control costs and improve quality. Under the shared savings program the incentives inherent in fee-for-service (FFS) Medicare to increase volume will still be operative and will have to be offset for ACOs to control spending and increase quality. Providers sharing risk with Medicare for cost growth for their patients will strengthen the incentives in the program to control volume and we support moving the program in that direction. The program could also help beneficiaries receive more coordinated care and become more engaged with their care management, particularly if beneficiaries are informed when they are assigned to ACOs, as we discuss further in our comments.

The proposed rule thoughtfully addresses many aspects of the program and discusses the pros and cons of different approaches. Among them are the specific qualifications ACOs must demonstrate, such as a clear management and leadership structure, clear arrangements to assure the continuum of patient care, and commitments to evidence-based and patient-centered care delivery. It also addresses assignment of beneficiaries to ACOs, quality, the shared savings models, coordination with other agencies concerning waivers and antitrust, and overlap with other CMS shared savings initiatives. The proposed rule addresses these issues and asks for comments on specific matters. In this letter, we comment on the following six areas that we think will be crucial to the program's success:

- Prospective assignment of Medicare beneficiaries so that they can be informed of their assignment to ACOs and become fully engaged with improved care management.
- Risk adjustment of the ACO population.
- Focusing on a set of quality measures that reflect the outcomes ACOs are designed to achieve.
- Assessing benchmarks, spending and savings at some form of standardized prices.
- Allowing assignment based on primary care provided in RHC, FQHCs, and by non-physician practitioners.
- Extending the one-sided risk model while protecting against random variation.

Our comments are intended to simplify the program and reduce uncertainty and administrative burden for providers who may wish to form ACOs. Providers may be reluctant to commit time and money to reorganize the delivery system to better coordinate care and improve quality, if rewards are uncertain and difficult to calculate. Our comments on assignment, risk adjustment, quality, and how to reduce initial administrative costs may help address those concerns. However, even if these changes were implemented in the final rule, the number of ACOs participating in the program may start small and grow slowly. Creating a well-functioning ACO will require a significant investment of money, effort, and time and the traditional FFS program will still be an attractive alternative; particularly for providers who are accustomed to being rewarded for the volume of services they individually provide and are proficient at increasing volume. Therefore, it would be a mistake to assess the success of the shared savings program by counting how many ACOs participate in the initial agreement period. Making the ACO terms generous enough to lure a large number of ACOs into the program could mean a high percentage of ACOs failing to achieve savings for Medicare and also failing to deliver their patients high quality, coordinated care. It is not in the long-term

interest of the shared savings program, or of Medicare more generally, to encourage participation by organizations that are unlikely to be successful. The program should not be expected to quickly transform the entire health-care delivery system. However, as a program that builds gradually, it could be an important step toward sustainability for the Medicare program if carefully designed to meet the goals of high quality care and slower growth in spending.

ACOs could play a central role in shifting the health care delivery system to one emphasizing quality and value to the benefit of the Medicare program, its beneficiaries, and taxpayers. However, the organization of care and care decisions will have to change if improvements are to be realized. Shifting from volume-driven to value-driven care will not be quick or easy, and it cannot be expected that a single set of regulations will be able to address all contingencies or difficulties that may arise. Therefore, it is crucial that the program be able to evolve and adapt over time. As ACOs gain experience with the program they may be able to provide guidance about what works and what does not to other ACOs and to organizations considering whether to join the program. CMS will need to make data available to the ACOs and entities such as MedPAC to help CMS determine the strengths and weaknesses of the different shared savings models and what aspects of the regulations may need to change. MedPAC also stands ready to help if technical clarifications or other legislative changes are needed. CMS should also take the opportunity to use the CMMI when that would be the most fruitful avenue to experiment with payment designs and move the program forward. The recently announced Pioneer ACO demonstration should be helpful in this regard and is in keeping with the tenor of many of our comments on the shared savings program. Providing an opportunity for experimentation in at least the initial years of operation of the shared savings program is another approach that we discuss in our comments on the one-sided model and quality reporting.

ACOs represent an opportunity to transform the delivery system, but realizing that opportunity will require providers to change their practices and take a risk on a novel payment system and CMS to be flexible and responsive as the program evolves.

We use the terminology of the proposed rule where possible. Briefly, the key terms are: an **agreement** period for each ACO consists of three **performance** years. An initial spending

benchmark is computed using three years of Medicare spending for the beneficiaries assigned to the ACO. Each year, an **update** amount is added to the prior year's benchmark to create a new benchmark for the performance year. That benchmark is then compared to actual Medicare spending to compute any **savings** or **loss**.

Assignment of beneficiaries to ACOs

The proposed rule asks for comments on whether beneficiaries should be assigned to ACOs prospectively, that is, before the performance year, or retrospectively, that is, after the performance year. It discusses arguments on both sides and comes down on the side of retrospective assignment because the evaluation of effectiveness will be on the population actually served while at the same time the ACO providers, not knowing for sure which beneficiaries are in their ACO, will treat all patients the same way. It also proposes sharing aggregate beneficiary level-data on those who would have been assigned in the benchmark period prior to performance measurement so that the ACO will have some idea of those who might be assigned to it in the performance period.

Comment

In any new Medicare program the rights and responsibilities of Medicare beneficiaries should be a primary consideration. Beneficiaries should know if their health care providers are operating under a new incentive structure. At the same time, for an ACO program to work well, beneficiaries will need to have greater engagement in their own care management. Properly structuring how the beneficiary is informed of his or her assignment to an ACO provider could help accomplish both of these goals but that will require prospective assignment. Prospective assignment will also improve adjustment for risk and quality reporting as we discuss in later sections of this letter.

Not informing beneficiaries would run the risk of a repeat of the managed care "backlash" experienced in the 1990s. The backlash resulted from patients feeling that they were being forced into managed care by their employers and that the financial benefits were accruing to employers health plans, or providers, not them. Some providers, many of whom were losing revenue due to managed care, were more than willing to feed patient concerns that the savings from managed care were being produced at the expense of the quality of care. This toxic combination of concerns

resulted in the backlash: it behooves Medicare to pay close attention to patient notification so as not to repeat history.

Beneficiaries will have to be assigned prospectively if they are to be informed of their assignment to an ACO before care is delivered to them under that model. Prospective assignment uses claims data from a prior year to make the assignment. An ACO would first identify its primary care provider members to Medicare. Medicare would then assign beneficiaries to the ACO whose primary care had been provided in prior years by those members. The proposed rule argues that retrospective assignment is superior to prospective. Retrospective assignment would use data from the performance year to make the assignment. However, if retrospective assignment were used, neither the ACO nor the beneficiary would know at the beginning of that year who was assigned to the ACO and prior notification would be impossible.

We suggest that the beneficiaries be informed and, unless beneficiaries indicate otherwise, they remain in the ACO. If they decide that the change in incentives for their provider makes them too uncomfortable, Medicare should provide them some choice. One choice that the beneficiary always has is to switch from the assigned primary care provider to another provider who is not in an ACO. Another choice, some suggest, is to allow beneficiaries to stay with their providers who are in the ACO yet "opt out;" that is, not have their data count toward the ACO's performance. This differs from the option allowed beneficiaries in the proposed rule which only allows a beneficiary to decide whether their provider should be given their data and does not give the beneficiary the option to opt out of the ACO and stay with their primary care provider. On the one hand, the opt-out option we propose would give the beneficiaries more choice and allay worries they might have about the incentives in ACOs. On the other hand, allowing beneficiaries to opt out creates administrative complexity for CMS and an opportunity for the ACO to discourage participation by complex, costly beneficiaries who could harm the ACO's performance.

In our approach, beneficiaries would have to make an active decision to opt-out, otherwise, their data will be part of the ACO's evaluation. As has been seen in other programs such as assignment into Part B by the Social Security Administration (94 percent accept assignment), beneficiaries with a low-income subsidy into Part D drug plans, and private-sector employees into retirement

plans, the opt-out approach preserves choice while preventing low take-up rates. A similar approach should be taken if CMS continues with retrospective assignment, essentially extending the data opt out mechanism in the proposed rule to include removing the beneficiary's data from the ACO's performance. If opting-out is allowed, an ACO's opt-out pattern should be examined annually. CMS should reconsider an ACO's participation if it is unable to retain a high percentage of its beneficiaries or if only beneficiaries with certain characteristics tend to opt-out.

Finally, notification should strengthen beneficiaries' engagement with their care management. Many think that patient engagement in programs such as home monitoring and shared decision making and in keeping their primary care provider informed will be essential for ACOs to succeed. Part of the notification process should inform beneficiaries of their opportunities and responsibilities to influence their own health and the health care coordination that the ACO is offering.

Risk adjustment of the ACO population

Risk adjustment in the Medicare program is designed to account for the effect that demographic characteristics and health status have on expected Medicare spending. The **update** amount in the shared savings program is proposed to be "the projected absolute amount of growth in per capita expenditures" [p. 19611]. This is essentially the expected growth in Medicare spending for a beneficiary with a risk score of 1.00, the national average risk score. Because it is using this amount as the update, the proposed rule needs to adjust an ACO's **benchmark** by its population's risk score to preserve equity among ACOs with populations that have different risk characteristics. That is, the update and the benchmark have to be consistent. The proposal uses the prospective HCC model to create risk scores for each beneficiary in each ACO as it does for each beneficiary in each MA plan.

The proposed rule sets the initial benchmark for an ACO according to the spending for the beneficiaries who would have been assigned (retrospectively) to that ACO in the three years preceding the agreement year adjusted for the average risk score of the assigned beneficiaries.[1]

[1] The actual calculation is more complicated including truncation of unusually high spending for an individual beneficiary, weighting by year, and other adjustments.

The risk score is then not updated in the agreement years, rather the risk score for the initial benchmark panel is kept unchanged even if the beneficiary population changes. This approach eliminates the incentive for an ACO to optimize coding, that is, to report as many diagnoses as possible for its patients and hence increase their risk scores because, the risk score is calculated based in part on the number and severity of diagnoses. The Commission shares CMS's concerns regarding coding optimization and its effects, however, the Commission is also concerned that this approach creates incentives for the ACO providers to encourage expensive patients to seek care elsewhere and to avoid new expensive patients. It also disconnects the benchmark spending from the beneficiaries who are actually assigned to the ACO. CMS considers another option which would tie expected spending more closely to the assigned beneficiaries. However, CMS concludes that the additional adjustments needed in the second option would outweigh its benefits and propose using the first option described above. We propose a modified version of the second option below.

Comment

We suggest that expected spending should be tied to the assigned beneficiaries, and that incentives to avoid high-risk beneficiaries and optimize coding should be minimized to the extent possible. We describe an approach that does so later in this section. Figure 1 compares the incentives in the proposed rule with the incentives in the approach we suggest. It is important to remember that if ACOs are to save money for the program they will need to focus on patients who are high cost to the program. As shown in Figure 1, those high-cost patients can be either those who are high-cost and high-risk or those that are high-cost and lower-risk. We need incentives for ACOs to want to retain patients who are high-cost and high-risk because they can improve care coordination for those patients and thus reduce avoidable spending (e.g., preventable readmissions) and improve quality. We also want ACOs to have an incentive to recruit patients who are lower risk but have been high cost because they have been treated inefficiently by other providers.

Figure 1. Potential for savings from ACO

	Low	Medium	High
	Low cost/low risk patients little scope for near-term savings	High-cost/high-risk patients could benefit from care coordination	High cost/lower–risk patients could benefit from more efficient care
CMS incentive	Attract these patients	Discourage these patients from using ACO physicians	Discourage these patients from switching to ACO practice
Revised incentive	Neutral	Keep these patients	Recruit these patients

The proposed rule incentives would encourage ACOs to avoid new patients who are expected to be high-cost patients, and possibly to make their practice less attractive to new patients with complex needs. Yet these are the patients who have the greatest potential for savings. CMS should consider an approach to risk adjustment that would create incentives to keep and recruit those very patients and allow the ACO to concentrate on patients with the greatest potential for savings, which would benefit both the program and the ACO. The approach should have four key objectives:

- Acknowledge differences in resource needs of patients treated by different ACOs.
- Create an incentive for the ACO to accept new complex patients who need care coordination and to continue to develop and maintain the capacity to treat those cases.
- Create an incentive to attract patients away from inefficient providers and those involved in inappropriate billing of services
- Minimize the effect of variations in coding intensity on payments.

The current method does not meet the first three objectives.

To meet these objectives, benchmark spending could be based on the assigned patients' historical spending and their individual historical risk score. Patients that have historically used more resources (risk adjusted) prior to the start of the three year agreement period would have higher benchmarks. New patients, those assigned in years two or three of the performance period, would bring their historical spending and risk scores with them. ACOs would have an incentive to serve patients with high benchmarks and attract new patients from inefficient providers because the high benchmark follows the patient. However, adjustments to the benchmark for continuing patients would change over time only to the same extent as the spending of a similar (i.e., similar

age/gender/conditions) population of FFS beneficiaries at the national level would be expected to change.[2] ACOs would not be rewarded with a higher benchmark if their patients grow sicker faster than expected compared to national rates and will not be penalized if they keep their patients healthier than expected. In other words, additional coding of conditions over the three years will not affect payment. Coding optimization had a large effect on the savings calculation in the PGP demonstration and the Commission agrees with CMS that it is important that its effects be minimized in the shared savings program.

Benchmarks could be calculated prospectively if there were prospective assignment. Knowing their benchmark in advance would help the ACO to monitor its progress on spending. Some adjustment would need to be made at the end of the year for beneficiaries who move or join MA plans.

On balance, we think this approach would be more equitable because it would tie benchmarks more closely to the assigned beneficiaries; would give ACOs an incentive to do what they should do best, take care of more complex patients who would benefit the most from care coordination; and minimize the incentive to focus resources on coding optimization.

[2] Under this approach, using the claims history of each beneficiary assigned to the ACO, one could use the variables in the HCC calculation to characterize each beneficiary in the ACO and match them to similar beneficiaries in the overall FFS population. Let us call that set of similar beneficiaries group R. One could then compute how the spending for group R has grown historically compared to average spending growth in the overall FFS population. This differential growth rate would be the amount allowed beyond the update for beneficiaries in the ACO with characteristics similar to group R. Because the assignment to group R is based on the beneficiary's historical spending and claims it would not change due to coding changes in the performance period. Technically, the differential growth rate, plus one, multiplied by the beneficiary's prior benchmark, added to the update, would yield the beneficiary's new benchmark. The ACO's benchmark would be the average of its beneficiaries' benchmarks.

Conceptually, this approach is similar to that proposed for the Pioneer ACO demonstration. In both cases the goal is to make the update consistent with the benchmark and only allow for growth in spending similar to the growth observed in a matched cohort of the national FFS population. (This is different from the PGP demonstration in which target spending was based on the concurrent performance of a comparison group drawn from the local area. Instead, benchmarks would be based on historical cost growth of similar patients in the national FFS population, not a local comparison group.) In the Pioneer ACO demonstration, the adjustment is made to the update. In the shared savings program, because the update is specified in statute, the adjustment has to be made to the benchmark.

Quality measurement and scoring

In both the one-sided and two-sided risk models, the ACO's final sharing rate will be determined by how well the ACO performs on a set of quality measures, regardless of the amount of cost reduction. CMS proposes to use 65 quality measures across 5 domains of care to calculate an ACO's sharing rate. The 5 measure domains are:

- Patient/caregiver experience (7 measures)
- Care coordination (16 measures)
- Patient safety (2 measures)
- Preventive health (9 measures)
- At-risk populations/frail elderly health (31 measures)

CMS proposes that each measure would be weighted equally within a domain, and each domain would be weighted equally in calculating an ACO's total quality performance score.

In year 1 of the ACO's agreement period, CMS would only evaluate whether an ACO reported on all of the required quality measures; the ACO's actual performance on the measures would not be used in calculating the percentage of shared savings or penalties the ACO receives, only whether the ACO achieved 100 percent complete and accurate reporting on each measure. An ACO's actual performance on the measures would be used in years 2 and 3 of the agreement period. The ACO's performance on each measure for its assigned beneficiary population would be compared to FFS or MA national benchmarks if such exist for a given measure, or compared against an absolute percentage threshold (for example, 30 percent, 40 percent, 50 percent, etc.). If an ACO fails to meet the minimum performance standards in any domain, it has one year to improve its performance or its contract with CMS will be terminated. Failure to report on a quality measure or reporting inaccurate information also could result in contract termination.

The ACO's performance on each measure relative to the benchmark would be converted into a point score, ranging from 2 points for performance over the 90^{th} percentile or 90 percent, stepping down in equal increments to zero points if the ACO's performance on a measure is below the 30^{th} percentile of the MA or FFS benchmark or below 30 percent if there is no comparable benchmark.

The sum of these "quality points" would be used to calculate the score in each domain and then the domain scores would be averaged to determine the percentage of the available shared savings or losses the ACO would be awarded. For example, if there were 10 measures in a domain and an ACO achieved 18 quality points out of the total of 20 possible points (equal to 10 measures times the maximum of 2 points each), it would receive a 90 percent score for that domain. If it did the same for all domains it would receive 90 percent of the ACO's share of the available shared savings (for example, in the standard 2-sided risk model, this ACO would receive 90 percent of 60 percent of the shared savings, or 54 percent). This approach is referred to as the quality performance standard option.

Comment

The Commission appreciates the need for CMS to be vigilant in ensuring that providers participating in an ACO do not stint on clinically necessary care in response to the economic incentives inherent in the design of the shared savings program. However, providers are less likely to participate in the program if the costs of creating and maintaining an administrative structure to meet CMS's participation requirements are too high. We are concerned that the proposed quality measurement and reporting requirements would create an unnecessarily high barrier to providers' participation in the program, especially in the start-up stages of the program, and that the scoring method creates undue financial uncertainty.

Quality measurement

To simplify quality reporting we urge CMS to consider using a much more focused set of quality indicators that reflect the outcomes ACOs are designed to achieve: keeping the population healthy, better care coordination to reduce unnecessary and sometimes harmful spending, and better patient experience. To that end, we support most of the proposed health outcome and patient experience measures, but suggest that CMS significantly reduce the number of required clinical process measures (Table 1). The agency should also decrease the administrative burden of data reporting for the remaining process measures by using measures that can be calculated using claims data, at least for the first few years of program implementation. CMS could use a small number of claims-based measures that report rates at which the ACO provides clinically-indicated services to its

patients with certain diagnoses prevalent among Medicare beneficiaries. This approach would be similar to that the Commission uses to annually evaluate the aggregate quality of physician and other ambulatory care services with the Medicare Ambulatory Care Indicators for the Elderly (MACIEs).[3] We have also recently discussed the feasibility of adapting some Healthcare Effectiveness Data and Information Set (HEDIS) measures that could be calculated using claims data, which is another option for CMS to consider for the ACO program.[4] We estimate that the number of measures could be reduced from 65 in the proposed rule to as few as 18 if only the proposed patient experience and outcome measures were used, or up to 40 if all of the proposed process measures that could be calculated using claims data also were included.

When determining the final set of measures, CMS also should address the balance in the number of measures in each quality domain. If each domain score is weighted equally when they are averaged to compute an ACO's final percentage of available shared savings or losses, individual measures in effect will have more or less weight depending on the total number of measures in the domain. Individual measures in a domain with few total measures will have more weight in the quality score calculation, and vice versa. In the proposed rule, the number of measures in the domains ranges from 2 in patient safety to 31 in the at-risk populations domain. (However, of the two patient safety measures one is a composite of 10 individual measures, the other is a composite of eight measures—simple counts may be misleading.) If CMS reduces the total number of measures, we suggest that CMS also consider carefully balancing the number of measures across the domains to create an incentive for equal clinical focus across a parsimonious final set of measures.

After a period of initial implementation experience and learning by both the agency and ACOs, CMS could, if needed, add more complex measures, for example, intermediate outcome measures that require data from clinical records, such as laboratory test results, as ACOs deploy the health information technology and other administrative capabilities needed to efficiently and reliably capture and report clinical record-based measurement data. CMS could also retire some measures as outcome measures are refined and experience builds confidence in their use.

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[3] *Report to the Congress: Medicare payment policy.* MedPAC, March 2011.
[4] *Report to the Congress: Medicare payment policy.* MedPAC, March 2010.

Table 1. Comments on proposed quality measures by quality domain

Domain: Summary comments	**Detailed comments**
Patient/Caregiver Experience: Support as proposed	We support the use of the proposed measures from the Clinician/Group Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey and the Medicare Advantage (MA) CAHPS survey. Patients may be more willing to stay assigned to the ACO if they know the provider's payments are dependent on patients' review of the quality of care provided. To complement the proposed ambulatory care and overall health status questions, CMS also may wish to consider adding an item from the Hospital CAHPS survey to measure the quality of the hospital patient experiences of ACO members, such as the "overall rating of hospital" question.
Care Coordination: Support with exceptions noted	We strongly support the proposed 30-day readmission rate, post-discharge physician visit and medication reconciliation measures, Care Transition Measure survey, and the AHRQ Prevention Quality Indicators (ambulatory care-sensitive condition admission rates).
30-day mortality rate: Add as complement to 30-day readmission rate	In addition to the proposed all-cause 30-day readmission rate, we urge CMS to add a parallel risk-adjusted all-cause 30-day post-discharge mortality rate. Using readmission rates alone may give an incomplete indication of the quality of care provided to beneficiaries during and in the critical transition period following an inpatient stay.
AHRQ admission rate measures: Analyze reliability with small sample sizes; use only reliable individual measures or combine into composite measure	For the AHRQ admission rate measures (PQIs), we observe that there may be very small sample sizes available for some of these measures in smaller ACOs and in all ACOs for a few of these measures, such as admissions for dehydration, which have relatively low prevalence and incidence across even the entire Medicare population. Very small sample sizes will decrease the statistical reliability of the measures and therefore increase the chance that observed differences in rates will be due to random variation. To address this problem, CMS could either drop the PQIs that have the least statistical reliability, combine the proposed PQIs into a composite "multiple-cause" ambulatory care sensitive admission rate measure, or use statistical techniques such as shrinkage estimation to increase the reliability of the measure.
Medicare EHR and e-Rx Incentive Program measures: Do not use	We do not support the proposed inclusion in this domain of five measures that would be based on the Medicare Electronic Health Record (EHR) and e-Prescribing Incentive programs. The individual physicians in an ACO already will have incentives through those two programs to become "meaningful users" of EHR systems and to use electronic prescribing for all of their Medicare patients, while including these measures in the shared savings program as well would discourage less technologically-sophisticated providers from attempting to implement an ACO. It may be challenging for an ACO to improve the quality and efficiency of care delivery without an interoperable EHR system, but the implementation of specific care delivery innovations should be decisions left to the providers who come together to form an ACO, with Medicare focused on measuring and publicly reporting the resulting improvements in health outcomes and cost growth reductions.
Patient Safety:	The Commission is concerned about recently published studies indicating that rates

Support, with exceptions noted below	of health-care acquired conditions (HACs) and other patient safety incidents remain unnecessarily high and that progress in improving patient safety has been slow.[5] We therefore support the inclusion of patient safety measures in the shared savings program with the exceptions noted below. The use of a composite measure for this domain is reasonable since the number of patient safety incidents in an ACO's covered population likely will be too small to yield statistically reliable results if these measures are calculated individually.
Serious reportable events: Include as proposed	The first five measures on the proposed list of HACs—foreign object retained after surgery; air embolism; blood incompatibility; pressure ulcer stages III and IV; and patient falls and trauma—are classified by the National Quality Forum as "serious reportable events" (SREs), formerly called "never events." To focus ACOs on the reduction and ultimately elimination of these patient safety events, we support the inclusion of these proposed measures, and urge CMS to expand the list to include additional SRE measures that have been endorsed by the National Quality Forum, such as patient death or serious injury associated with medication errors, and death or serious injury resulting from failure to follow up or communicate clinical information, as soon as practicable. Because the data for these measures would be collected from claims, including them would not increase the administrative burden on ACOs, but CMS would need to monitor the potential unintended consequences of creating a disincentive for providers to report SREs on claims.
Hospital-Acquired Infections: Use ongoing HAI reporting through CDC's National Healthcare Safety Network	CMS proposes to include three individual measures of hospital-acquired infections (HAIs) in the HAC composite measure: central line-associated bloodstream infection (CLABSI), catheter-associated urinary tract infection (CAUTI), and surgical site infection (SSI). CMS has already specified a CLABSI measure for hospitals that participate in the Medicare Hospital Inpatient Quality Reporting (IQR) Program (built on the reporting infrastructure of the CDC's National Healthcare Safety Network (NHSN)). CMS will include an NHSN-based SSI measure in the IQR Program in 2012 and has proposed to add a CAUTI measure in 2013. As CMS brings these measures on-line for use in the Hospital IQR Program, we urge CMS to use the same infrastructure for the collection and reporting of all three of these HAI rates for the shared savings program. Using claims data to calculate HAI rates, where there will be an incentive to under-report their occurrence, exacerbates the reliability problem. It would be more accurate and efficient to use the CDC/NHSN mechanism that CMS will implement over the next few years for these three types of HAIs.
Manifestations of poor glycemic control: Evaluate current clinical evidence underlying measure specifications,	The proposed HAC measures include "Manifestations of Poor Glycemic Control," which we are concerned may not meet our long-standing principle that CMS should use only widely-accepted, evidence-based measures for all Medicare quality-based payment and public reporting. Concerning this particular measure, research published within the last two years suggests that the use of clinical interventions to maintain glycemic control in some patients, especially the frail elderly, may adversely affect patient health outcomes.[6,7] We urge CMS to carefully consider the

[5] MedPAC comment letter on proposed rule for Medicare Hospital Value-Based Purchasing Program, March 4, 2011.
[6] Montori, V. M. and M. Fernández-Balsells. 2009. Glycemic control in type 2 diabetes: Time for an evidence-based about-face? *Annals of Internal Medicine* 150, no. 11 (June 2): 803-808.
[7] Lee, S. J. and C. Eng. 2011. Goals of glycemic control in frail older patients with diabetes. *Journal of the American Medical Association* 305, no. 13 (April 6): 1350–1351.

modify or delete as indicated	most recent clinical evidence on glycemic control for hospital inpatients and older patients with multiple comorbidities before deciding whether to use this measure.
AHRQ patient safety indicators composite: Do not use because of duplication of other HAC measures, statistical concerns	If the HAC measures discussed above are included in the HAC composite measure, it seems duplicative to also include the proposed AHRQ Patient Safety Indicator (PSI) composite measure. Several components of the proposed PSI composite measure overlap with the other HAC measures. ACO providers may find the individual or composite AHRQ PSI measures useful for internal quality improvement activities, but we are concerned with the statistical reliability of the AHRQ PSI measures in the context of affecting individual ACOs' bonuses or penalties.
Preventive Health and At-Risk Populations: Reduce number of measures and use only claims-based process measures for initial 3-year contract period	Illustrative examples of proposed measures that could be used consistent with our suggestion to use only claims-based process of care measures include the following: influenza immunization and pneumonia vaccination rates; breast and colorectal cancer screening rates; rate of cholesterol management of patients with cardiovascular conditions; rates of eye and foot examinations for patients diagnosed with diabetes; rate of left ventricular function testing for patients hospitalized with principal diagnosis of heart failure; prescription for certain kinds of drugs for patients with coronary artery disease.

A few of the proposed measures would be based on hospital claims data (which CMS calculates) or data reported by hospitals through the CDC National Healthcare Safety Network (NHSN). We agree that these measures of hospital patient safety and hospital-acquired conditions should be included in the ACO quality measure to focus ACOs on reducing or eliminating these avoidable and clinically serious events for their patients. To minimize the administrative burden of reporting on these measures for small ACOs or those that do not include a hospital, CMS could leverage its existing quality measurement data, such as having all hospital-level measures be based on data already collected for the Hospital Inpatient Quality Reporting program for all of the hospital's Medicare patients. CMS then could compute a weighted average of the quality scores of the hospitals used by the ACO's patients to ensure that the ACO was admitting its patients to high quality hospitals. This approach would enable ACOs that do not include hospitals to report hospital measures easily, and it would avoid the small numbers problem that otherwise could occur when these measures of very rare events are computed solely on the basis of each ACO's admitted patients.

Quality scoring

CMS should simplify quality reporting and reduce uncertainty regarding the quality scoring. To reduce uncertainty, we suggest that CMS use a modified version of the quality threshold approach discussed in the proposed rule. As the rule states:

> "A threshold established at a basic level of quality acknowledged to be minimally necessary presents less of a risk of being triggered due to random variation, as opposed to truly poor performance. Finally, for ACOs meeting the threshold, their shared savings percentage attributable to quality would be fixed and certain. This would increase incentives, achieve savings, and present more certainty on potential investment returns for organizations considering whether or not to become ACOs." [P.19597-8]

We agree with this logic and find that the advantages of the quality threshold option (compared with the proposed quality performance standard option) would outweigh any disadvantages cited, particularly in the early years of the program.

A threshold approach could work as follows. First, CMS could tell each ACO what the historical 50^{th} percentile has been for each quality metric in prior years. The ACO then would have to exceed this benchmark in each of the five domains to fully share in savings. For each domain in which it exceeded the benchmark, its share of savings would increase by 20 percent of the maximum shared savings percentage. This would give the ACO certainty over the targets it needs to achieve and reduce the uncertainty over its financial liability, which plagues the proposed quality approach. Whatever the ACO score on the quality metrics, the ACO is still responsible for its share of losses under the two-sided model. The proposed rule sets the loss sharing at one minus the actual savings share. That design can lead to asymmetries in the model. For example, if the quality score were 40 percent and the maximum shared savings rate were 60 percent, the share of savings would be the product, 24 percent. The share of loss would be one minus the share of savings, or 76 percent. The Pioneer ACO demonstration also recognizes this asymmetry as an issue. Our alternative design would set the share of losses equal to the maximum sharing rate because that would reduce uncertainty and the expectation would be that ACOs will likely be above average on all five domains most of the time.

Assessing benchmarks, spending and savings at standardized prices

The proposed rule asks for comment on whether or not to take into account factors such as the Medicare wage index and teaching payments to hospitals when calculating benchmarks, spending, and savings (or losses). The proposed rule does not take these factors into account primarily because the statute states that **benchmarks** "…shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate…" but the only adjustment specified for the **expenditures** used in the savings calculation is "...for beneficiary characteristics,…" The proposed rule concludes that the Secretary does not have authority to adjust expenditures for other factors.

Comment

We suggest that two underlying principles should be kept in mind when considering this issue. First, the benchmark, expenditures, and update should all be consistent to the extent possible. Second, ACOs should primarily be judged on their success in controlling the growth in service use by their patients isolated from changes in prices (such as input prices in their markets) that may be outside of the ACOs control. Maintaining these two principles will be crucial to create a shared savings program that is equitable for ACOs in different parts of the country and that use different mixes of providers. Given the importance of this calculation, we think it is critical that CMS reexamine whether it has the authority to follow these principles and if it determines it does not, CMS should seek a statutory change that would grant the agency this authority; and MedPAC will also pursue this legislative change.

To the first principle, because the update is specified as the projected absolute increase in national per capita spending, the benchmark and spending should be standardized so that they will be consistent with the update. For example the update essentially incorporates the national average wage index, GPCI, and other geographic price adjusters. Standardizing ACO spending for those geographic adjusters would be equitable because it would remove any advantage or disadvantage from an event outside the ACO's control, namely the input price for labor in their region. Similarly, Medicare makes adjustment for additional products such as teaching through the IME

factor, technology adoption through special DRG adjustments, and other policy goals such as access in rural areas through factors such as special payments to CAHs. Standardizing for these policy factors would be more equitable as well because those special payments are not for the service provided but to achieve other policy goals—which we would not want to discourage ACOs from achieving. The method used to standardize ACO spending could follow that laid out in our recent report on geographic variation.[8]

To the second principle, concentrating on service use, two examples may indicate why adjusting for prices is important. For example, assume a group practice operates in an area where the hospital has a wage index exception. The exception expires, and then hospital payments fall by 8 percent. This should not be a reason for the group practice to receive a bonus. Likewise, imagine a group of physicians operating in a rural area served by a midsize hospital and two small hospitals. The small hospitals convert to CAH status and that allows the midsize hospital to convert to sole community hospital status and hospital payments go up by 10 percent. That should not be a reason to assess the group with a penalty. To avoid allowing idiosyncrasies and fluctuation in prices over time to affect bonuses and penalties, the ACO program should make adjustments for input prices and special payments.

Using historical service use to adjust the maximum savings rate

Once the level of service use is computed, it might then be more equitable to adjust the rewards for ACOs that have already achieved relatively low service use levels. One approach could be to allow such ACOs to obtain a larger share of the savings by increasing the maximum savings rate for ACOs with the lowest service use. Those ACOs could for example, have a maximum savings rate of 75 percent in the one-sided model or 95 percent in the two-sided model. ACOs with higher baseline service use would have a lower maximum savings rate. This approach would recognize that ACOs with lower service use may have less scope for efficiency gains than other ACOs and thus, increasing their share of savings might help increase equity across ACOs.

[8] *Report to the Congress: Regional variation in Medicare service use.* MedPAC, January 2011.

Assignment based on only primary care services provided by a primary care physician

Under the proposed rule assignment is based on the primary care physicians who account for the plurality of primary care charges, and the primary care physician has to be exclusive to one ACO. Assignment is not extended to specialist physicians or to non-physician practitioners such as nurse practitioners, advanced practice nurses, or physician assistants. Rural health clinics and FQHCs are also not used for assignment. To encourage use of FQHCs and RHCs, CMS increases the percentage of savings ACOs can get based on percent of assigned beneficiaries with one visit or more to an FQHC or RHC in the ACO and reduces the additional threshold in the one-sided model on a similar basis.

Comment

CMS points out that the statute specifies that assignment be based on "…utilization of primary care services provided under this title by an ACO professional described in subsection (h)(1)(A)." An ACO professional described in (h)(1) could be either a physician or a practitioner, but (h)(1)(A) refers to physicians only. In addition to restricting assignment to physicians, the proposed rule further restricts assignment to primary care physicians because it would be consistent with other provisions in PPACA and because it "… places priority on the services of designated primary care physicians (for example, internal medicine, general practice, family practice, and geriatric medicine) in the assignment process." The Pioneer ACO demonstration explicitly adds nurse practitioners and physician assistants to the definition of primary care provider. It also creates a second step in the assignment algorithm allowing beneficiaries to be assigned to specialist physicians under certain circumstances. A step-wise option is also discussed in the proposed rule but is not the preferred option because it would increase complexity and require specialist to be exclusive to one ACO, even though it might increase the number of beneficiaries assigned.

The Commission prefers a more expansive definition of providers who could be assigned beneficiaries to increase the number of beneficiaries assigned to ACOs and to recognize the role those providers play in patient care. For example, we would prefer the step-wise option which

assigns beneficiaries first to primary care physicians if possible and then to certain specialty physicians if the share of evaluation and management visits (or charges) to primary care physicians falls below a threshold value.[9] (The Pioneer ACO demonstration sets the threshold as 10 percent or less of E&M charges.) Although those specialists would have to be exclusive to one ACO for assignment purposes, they could still serve other patients who are either not assigned to ACOs or are assigned to other ACOs, thus the assignment exclusivity should not create access problems. The question of whether beneficiaries can be assigned to other practitioners should also be considered. Here again the Commission would urge CMS to reexamine its legislative authority, and if it determines that it is unable to pursue the broader definition for assignment, the agency should seek legislative clarification or the requisite authority and MedPAC will seek legislation as well.

It would also be more straightforward to allow assignment of patients to RHCs and FQHCs and encourage their use directly rather than to introduce special provisions for the savings share and thresholds as the proposed rule does. These are primary care provider teams often associated with a physician and usually providing primary care services. Logically they should be allowed to participate in ACOs and patients should be assigned to them. In many rural areas, RHCs function as primary care physicians' offices and, although they are paid differently under Medicare, they are still fulfilling the same function. In addition, under the proposed rule, beneficiaries could not be assigned to an ACO if they received all of their primary care services from RHCs. If many of the beneficiaries in an area were in this situation it would make it difficult to establish ACOs in such areas. A similar problem could be true in areas where many patients are seen by FQHCs. The proposed rule points out that an additional obstacle to assignment is that services in RHCs and FQHCs are generally paid on a flat rate and their claim do not specify whether they are for primary care services or not. We propose CMS posit that all claims in RHCs and FQHCs are for primary care services and use them for assignment as it would any other primary care claim.

[9] Assignment is to the group of primary care physicians in the ACO or the group of specialists in the ACO, not at the individual physician level.

Single-sided shared savings model

In the proposed rule a single-sided shared savings model is discussed that will last for two years and then transition to a two-sided model. It notes that a strictly one-sided model "…may not be enough of an incentive for participants to improve the efficiency of health care delivery and cost." The "hybrid approach" proposed is expected to allow organization to gain experience with population management before assuming risk. More experienced organization can choose to enter directly into a two-sided risk model that allows ACOs a greater share of savings in recognition of the greater risk that they accept.

Comment

Although the hybrid approach is reasonable in terms of moving to a program with stronger incentives for improving care, it may occur too soon for organizations that are uncertain of success. One possibility would be to give ACOs a choice to remain in the one-sided model through the three years of the first agreement period. Forcing ACOs to make too quick a transition could increase the risk of failure, and reduce participation. During those first years, CMS could analyze the data on performance and report on how the ACOs would have fared under a two-sided model and under different values for the savings percentage and other key parameters. CMS could also report on observed variation and use information on early adopters to inform subsequent regulations. Those follow-on regulations might make other models available and modify specifications for savings percentages and thresholds. This might make entry more feasible for ACOs with different characteristics than those in the early years as the parameters for success become more apparent.

To protect the taxpayer, if the one-sided model is extended, CMS would need to maintain the proposed minimum savings rates (MSR). Even with the currently proposed minimum saving rates and bonus thresholds there will still be some bonuses paid for random variation. The MSR and threshold are needed to limit the size of bonuses paid for random variation, and thus limit the risk of ACOs increasing Medicare costs. When offering the one-sided and two-sided models at the same time, CMS should also continue to assure that the two sided model is relatively attractive,

recognizing that ACOs are taking some risk in that model. The share of savings and other variables should be designed to take that into account.

While the time frame of the one-sided model should be extended beyond two years, the two sided model should be retained as an option and eventually should be the only option. Given the proposed rules, providers who have confidence that they can generate an annual one percent reduction in the growth rate of Medicare expenditures (cumulatively, three percent over the three year agreement period) will be better off under the two sided model rather than the one sided model. The Medicare program would also benefit from the stronger incentives to change practice patterns inherent in the two-sided model.

Improving the return on investment for ACO formation

When deciding whether to form ACOs, providers will weigh the prospect of bonuses against the costs of forming an ACO. Changing the ACO regulations to reduce the fixed costs of forming and operating an ACO will be necessary to attract providers to the ACO model. This will be particularly important for small ACOs. At the same time, increasing the share of savings going to providers beyond the maximum of 50 percent for the one-sided shared savings model or 60 percent for the two-sided shared savings model would improve the benefit side of the equation. For example, for the first agreement period the savings rate could be up to 75 percent for the one-sided model and 95 percent for the two-sided model. (CMS would need to retain the minimum savings rate and the thresholds to limit the cost of paying bonuses for random variation.)

The proposed rule already has two provisions that favor smaller ACOs without hospitals. First, small ACOs without a hospital have less stringent minimum saving rates (MSRs), allowing them a 10 percent chance of receiving a random bonus compared to a 1 percent chance for the largest ACOs. Second, under the bonus-only shared savings model, small ACOs with certain characteristics (such as only ACO professionals—no hospital) receive a share of first dollar savings if they meet their MSR, while large ACOs and those with hospitals receive a share of savings net of the first 2 percent of savings. For example a physician-only ACO with 5,000 beneficiaries that generates a 4% reduction in Medicare cost growth over two years would be

eligible for up to a 2% bonus (50% of 4%) while the same ACO with a hospital partner or a larger ACO would only receive up to 1% bonus (50% x (4% - 2%). Therefore, the bonus structure is already set up to favor small ACOs.

What will prevent small ACOs from joining under the proposed rule (and may prevent larger providers from joining also) are the high fixed costs of forming and operating an ACO. To that end, the final rule could:

- Shift quality reporting to metrics that can be measured with claims and hospital-reported data as discussed above.
- Reduce administrative requirements of forming the ACO, such as having CMS compute market share statistics to free ACOs from the administrative burden of evaluating their own compliance with the FTC safe harbors.
- Eliminate criteria concerned with the process of how an ACO operates such as requirements on board composition, method of distributing savings among ACO participants, and meaningful use of electronic medical records.

The general idea is that bending the Medicare cost trend downward is difficult, and thus ACOs will have to change practice patterns to succeed, and even then may have limited opportunities for savings in most markets in the near term. To make entrance into the shared savings program economically attractive for these providers, CMS should set a goal of keeping the annual administrative costs of operating ACO to less than one percent of Medicare expenditures per beneficiary. For an ACO with 5,000 beneficiaries this would be roughly $500,000. In other words, the marginal cost of adding an ACO to a group practice should be less than $500,000 additional dollars beyond what is currently spent on administration and compliance with other requirements such as PQRI and HIT. This would allow a high-quality ACO that generates two percent savings to receive more in bonuses than the cost of operating the ACO. While CMS should try to reduce administrative burdens on ACOs, CMS needs to maintain the MSR at its current level to prevent excessive bonus payments due to random variation in ACO spending. In

other words, CMS should make ACOs more attractive by reducing the cost of forming ACOs rather than lowering the thresholds that providers must achieve to share in savings.

One principle that should be followed is to focus on outcomes and not process for all aspects of the program, not just quality metrics. For example, we are interested in ACOs that work; not how their internal structure brings success about. Decisions on the structure of board membership and distributing savings bonuses within the ACO should be left to their discretion, not directed by regulation. Removing regulation that focus on internal processes within ACOs would simplify the regulation and decrease the costs of forming ACOs.

Conclusion

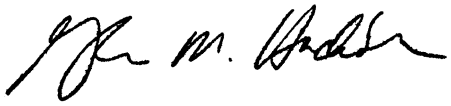
Taken together, a number of our comments should make the ACO shared savings program more attractive to smaller, physician led ACOs including those with no hospital participation. Streamlining quality reporting, particularly for hospital measures, should limit administrative burden on ACOs. Extending the one-sided model should remove the fear of having an unknown liability for the ACO participants. Allowing assignment to RHCs and FQHCs might make physician led ACOs more feasible in areas served by those providers. CMS could also coordinate with other agencies such as the FTC to reduce administrative burden on ACOs. Many of these steps could make forming ACOs a less capital-intensive process, which would remove a barrier for smaller, physician-led organizations. Finally, CMS could also consider creating demonstration of smaller, physician-led ACOs through the CMMI.

To increase the attractiveness of the ACO program to providers, CMS could reduce the costs of forming an ACO and could increase the share of savings going to providers beyond the current maximum of 50 percent for a one-sided shared savings model or 60 percent for the two-side risk sharing model. For example, for the first agreement period the savings rate could be up to 75 percent for the one-sided model and 95 percent for the two-sided model. However, CMS needs to retain the minimum savings rate and the thresholds to limit the cost of paying bonuses for random variation.

MedPAC appreciates your consideration of these policy issues. Thoughtful and effective regulations and demonstration designs will be necessary for ACOs to succeed. The Commission also values the ongoing cooperation and collaboration between CMS and MedPAC staff on technical policy issues. We look forward to continuing this productive relationship.

If you have any questions, or require clarification of these issues, please feel free to contact Mark Miller, MedPAC's Executive Director, at 202-220-3700.

Sincerely,



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