PUBLICATION

Final Medicare Shared Savings Program Regulations More Favorable to ACOs

November 16, 2011

In an effort to salvage the viability of the accountable care organization (ACO) concept and in response to the dissatisfaction voiced by the provider community regarding the requirements and incentives in the proposed Centers for Medicare and Medicaid Services' (CMS) ACO regulations, CMS has offered a more attractive means for providers to realize and share in savings while still maintaining the core elements of the originally proposed Medicare Shared Savings Program.[1] Whether the revisions are enough to entice providers to make the substantial investment in developing ACOs that will participate in the Medicare Shared Savings Program remains to be seen. This alert will highlight some of the more significant changes adopted by CMS in the final Shared Savings Program regulations.

No Risk Option. In the proposed regulations, CMS proposed two alternative payment tracks that ACOs could elect on their initial application to participate in the Medicare Shared Savings Program. The proposed Track 1 would allow ACOs to participate with no downside risk for the first two years with a mandatory conversion to a two-sided risk model in the third year, which would put such ACOs at risk to the extent that the actual year three expenditures for the ACO's assigned beneficiaries exceed the expenditure benchmark for the assigned population. In the proposed Track 2, ACOs would participate in the two-sided risk model for all three years of the participation agreement.

Many ACOs and providers saw the potential for downside risk during the initial three-year participation period as a significant barrier to participation especially in light of the limited savings realized by the highly-integrated participants during the first three years of operation of CMS' Physician Group Practice Demonstration Project. In the final regulations, CMS relented and revised Track 1 to allow ACOs to initially participate in a shared-savings only model.[2] ACOs still elect their participation track during the initial application process and may only elect Track 1 during their initial enrollment period. CMS also clarified that participation in the Medicare Shared Savings Program will be on a rolling basis so that ACOs that do not participate in 2012 will have an opportunity to participate in 2013 and beyond.

More Sharing Potential. Under the final regulations, ACOs will generally realize more savings under both Track 1 and Track 2. Most significantly, CMS eliminated the two percent savings threshold that it had proposed for Track 1 ACOs. As a result, so long as Track 1 ACOs achieve the minimum savings rate, which varies from 2 percent to 3.9 percent depending on the number of beneficiaries assigned to the ACO, they will share in first dollar savings up to 50 percent of any realized savings (depending upon the ACO's achievement of quality performance standards).

Because of the downside risk potential for all three years under Track 2, CMS had not proposed a similar two percent savings threshold for ACOs participating under Track 2. Track 2 ACOs that achieve the minimum savings rate, which is set at a flat two percent, will share in first dollar savings up to 65 percent of the overall savings, depending upon the ACO's achievement of quality performance standards.

CMS has also increased the performance payment limit (i.e., the maximum amount of shared savings that can be realized by the ACO in any given performance year) for both Track 1 and Track 2 participating ACOs to 10 percent and 15 percent, respectively.[3] This creates a real upside opportunity for those ACOs that perform at the highest level with respect to managing beneficiary costs while maintaining quality.

To encourage earlier participation, CMS will also pick up the costs of the ACO's patient experience of care survey for 2012 and 2013. Thereafter, such cost will be the responsibility of the ACO.

Providers should also receive earlier payment distribution of any earned shared savings as a result of CMS reducing the claims run out period from the proposed six-month period to three months.

CMS also eliminated the proposed 25 percent withhold of distributable shared savings for both Tracks, although ACOs that elect Track 2 (or interim payment) will still have to demonstrate an adequate repayment mechanism in the event they incur sharable losses.

The following chart summarizes the key payment provisions of the final regulations:

Issue	**Track 1**	**Track 2**
Minimum Savings Rate	2.0-3.9%	2.0%
Threshold	n/a	n/a
Shared Savings Rate	Max. 50%	Max. 60%
Performance Payment Limit (Cap)	10%	15%
Withhold	n/a	n/a
Minimum Loss Rate	n/a	2.0%
Shared Loss Rate	n/a	[1-Shared Savings Rate][4]
Maximum Shared Loss Rate (Cap)		Year 1: 5% Year 2: 7.5% Year 3: 10%

Quality Performance. The final regulations also eased the quality reporting burden by reducing the overall number of quality measures that an ACO must measure, report and achieve, from 65 proposed measures to 33 final measures. CMS will also continue to pay for reporting for certain quality measures in performance years two and three, as opposed to requiring the CMS proposed rule attainment levels for years two and three. With respect to future quality measures, CMS indicates that it anticipates a relatively static set of quality measures during the first agreement period.[5] ACOs that enter into an agreement period beginning after 2012 will be subject to the same quality measures and performance standards unless they are revised as a result of future rulemaking. For those ACOs impacted by statutory and regulatory quality measures and performance standards changes during the agreement period which the ACO believes will impact its ability to continue to participate in the Shared Savings Program, the ACO will arguably be able to terminate their participation agreement.[6]

Interim Payments. Due to the longer initial contracting period for ACOs that enter participation agreements in 2012, ACOs will be able to request interim payments based on their first 12 months of participation in the Medicare Shared Savings Program,[7] and CMS has indicated that it has passed on comments from providers regarding the need for financial assistance to cover the costs of developing ACOs to the Centers for Medicare

and Medicaid Innovation (Innovation Center). Certain ACOs participating in the Medicare Shared Savings Program may also qualify for the Advanced Payment ACO model.[8]

Beneficiary Assignment and Reports. CMS had originally proposed to assign Medicare beneficiaries on a retrospective basis based upon whether the beneficiary utilized primary care physicians participating in the ACO to receive a plurality of their primary care services. In the final regulations. CMS utilizes a step-wise process. First, CMS will assign beneficiaries by identifying all Medicare beneficiaries that had at least one primary care service furnished by a physician who is an ACO provider/supplier. The beneficiary will then be assigned to an ACO if the allowed charges for primary care services furnished by all the primary care physicians who are ACO provider/suppliers exceed the allowed charges for primary care services furnished by primary care physicians[9] who do not participate with the ACO. Second, for those beneficiaries that do not receive "primary care services" from any primary care physician in or out of the ACO, CMS will assign beneficiaries to an ACO on the basis of "primary care services" provided by an ACO specialist for beneficiaries. The same analysis used in step one will be used in step two. Additionally, FQHCs and RHCs, under a slightly different analysis and slightly different requirements, will be assigned beneficiaries based on services provided by their ACO attending physicians providing "primary care services."[10] CMS believes that by expanding the assignment process, more beneficiaries will ultimately be assigned to each participating ACO.

CMS will also assign Medicare beneficiaries on a preliminary basis at the beginning of each performance year. Such assigned beneficiary information will then be updated on a quarterly basis based upon the most recent 12-month data with final assignment being determined at the end of the performance year. The provision of more timely reports to ACOs should allow ACOs to better monitor beneficiary utilization and monitor whether the ACO is at risk for falling below the 5000 assigned beneficiary threshold.

EHR. CMS will no longer require that at least 50 percent of the ACO's primary care physicians be defined as meaningful users by the start of the second performance year as it had originally proposed.[11] This change was presumably to address the general concern that the costs of complying with this requirement would limit the opportunities for rural and physician-owned ACOs to participate in the Medicare Shared Savings Program.

Exclusivity. With respect to the exclusivity of providers, CMS clarifies that its proposed requirement that primary care physicians[12] by whom beneficiary assignment is established must be exclusive to one ACO during the three-year agreement period has changed. First, it is based on the step-wise beneficiary assignment process. Beneficiaries are assigned based on "primary care services" provided by a primary care physician, specialist or FQHC/RHC attending physician. Second, the exclusivity only applies at the level of the ACO participant's tax identification number (TIN). In other words, each ACO participant TIN upon which beneficiary assignment is dependent must be exclusive to one ACO. ACO participant TINs upon which beneficiary assignment is not dependent are not required to be exclusive to one ACO.[13]

Accordingly, the primary care services may be provided by a member of a group practice that is an ACO participant through which beneficiaries are assigned to the ACO. In such instance, the ACO participant's TIN, i.e., the group practice, would be exclusive to the ACO for three years, but the individual physician would be free to participate in additional ACOs by billing under different TINs or even leave the group and join another ACO so long as the physician is practicing elsewhere under a different TIN. However, for solo practitioners whose TIN is their social security number, these physicians could not change ACOs during the exclusivity period without associating with another ACO participant TIN and billing for services under that participant's TIN.[14]

Governing Body. The final regulations also provide greater overall flexibility regarding how an ACO may compose its governing body. Most notably, CMS has eliminated the requirement that each ACO participant must have proportional control of the governing body, and instead, CMS will require ACOs to provide ACO

participants with meaningful participation in the composition and control of the governing body. Further, CMS declined to set forth thresholds for physician, certain specialist, or skill set representation on the governing body. While CMS did maintain both the proposed requirement that ACO participants hold at least 75 percent control of the governing body and the requirement that at least one Medicare beneficiary receiving services from the ACO be included on the governing body,[15] CMS also provides a means by which ACOs can participate in the Shared Savings Program without satisfying these requirements.[16] The added flexibility of the final regulations will better allow ACOs to compose their boards in a manner to best suit their particular needs.[17]

Beneficiary Inducements. CMS also subjects ACOs to a new prohibition on beneficiary inducements in the final rule. Specifically, CMS prohibits ACOs, ACO participants, ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities from providing "gifts, cash, or other remuneration to beneficiaries as inducements" for receiving items or services from or remaining in an ACO or with ACO providers/suppliers in a particular ACO.[18] CMS does, however, provide an exception to this general prohibition that allows ACOs, ACO participants, ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities to provide beneficiaries items or services for free or below fair market value so long as there is a reasonable connection between the items and/or services and the medical care that the beneficiary is receiving and either preventive care items or services, or advance a clinical goal of the beneficiary such as a treatment regime, adherence to a drug regime, adherence to a follow-up care plan or management of a chronic disease or condition.[19] CMS has indicated that it will interpret this new regulation consistent with the waiver provisions for beneficiary inducements.[20] This additional guidance should assist ACOs in directing their resources in a manner so as to positively impact the health and overall health care costs of beneficiaries without fear of inadvertently subjecting the ACO and its participants to civil money penalties or other compliance concerns.

Conclusion. There are numerous other changes in the final regulations that merit discussion.[21] The question, however, is whether these changes are enough to rekindle provider interest in the Medicare Shared Savings Program. Although we believe many ACOs will decide not to participate in 2012, we believe that the final regulations may be enough to encourage ACOs to participate in the Shared Savings Program in 2013 and beyond.

If you have questions or need any additional information about how the final Medicare Shared Savings Program regulations may affect you or your company, please contact your Baker Donelson attorney.

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1. Centers for Medicare & Medicaid Services, Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, Final Rule, 75 Fed. Reg. 67802 (Nov. 2, 2011).

2. 42 C.F.R. § 425.600(a)(1). An additional benefit of the Track 1 option is that in those states that would treat an ACO that assumes risk for shared losses as being in the business of insurance, CMS' revised approach to Track 1 should make it cheaper for such ACOs to operate because it is highly unlikely that any state Department of Insurance will find a shared savings only model as requiring registration as an insurer under state law.

3. The performance payment limit is set at a percentage of the adjusted benchmark (i.e., the historical per capita Part A and Part B expenditures for beneficiaries that would have been assigned to the ACO).

4. The Shared Loss Rate is capped at 60 percent of the adjusted benchmark amount.

5. Updates may be made in future rulemaking as clinical guidelines change and other Medicare programs change their quality measures.

6. 42 C.F.R. § 425.212(d). An ACO is exempt from the following program changes within the term of their participation agreement: eligibility requirements concerning governance; calculation of sharing rate; and beneficiary assignment.

7. The ACO must specifically request an interim payment as part of its application; will have to demonstrate an adequate repayment mechanism (as consistent with those ACOs that choose to participate in the Track 2 two-sided risk model); will have to provide quality reporting information for the 12-month period; and will have to repay any losses created by such interim payments as part of the reconciliation of the first performance year. It also appears that ACOs requesting interim payment could have to make payment for interim losses if the ACO realizes a loss during the interim period.

8. In the interim between publication of the proposed regulations and the final regulations, the Innovation Center unveiled an Advance Payment ACO model but has restricted participation to certain rural and physician-owned organizations. In the final regulations, CMS suggests that the Advanced Payment ACO model may be expanded to cover different types of ACOs.

9. For purposes of the Shared Saving Program, CMS defines both "primary care physician" as well as "primary care services". See 42 C.F.R. § 425.20. Primary care services are now defined based upon specific procedure and revenue codes.

10. 42 C.F.R. § 425.402(a)(1)(ii). With respect to the remainder of the beneficiaries, i.e., those beneficiaries who have not received primary care services furnished by a primary care physician in or outside the ACO, CMS will assign the beneficiaries based upon whether the allowed charges for primary care services furnished by all ACO professionals participating in the ACO exceeds the allowed charges for primary care services furnished by all ACO professionals not participating in the ACO (or participating in another ACO). 42 C.F.R. § 425.402(a)(2). The final rule for FQHC or RHC for the separate Medicare beneficiary assignment process is found at 42 C.F.R. § 425.404.

11. CMS does adopt a quality measure requiring ACOs to report the percentage of primary care providers who successfully qualify as "meaningful users" under CMS' EHR Incentive Program.

12. Primary care physicians are defined for purposes of the Shared Savings Program Rule as those physicians practicing internal medicine, geriatric medicine, family practice, and in general practice.

13. That is, the obligation is at the TIN level, not the individual practitioner level (i.e., the National Provider Identifier (NPI) level). See 42 CFR § 425.306.

14. This assumes the solo practitioner TIN is an ACO participant upon which beneficiary assignment is based. Additionally, this exclusivity requirement is extended to cover specialist physicians providing "primary care services" as well as physician assistants and nurse practitioners for whom beneficiaries are assigned to the ACO.

15. 42 C.F.R. § 425.106(c)(5).

16. Specifically, an ACO that wishes to avoid the 75 percent control and/or beneficiary representation requirement must explain on its application why it seeks to differ from these standards and describe how the

ACO will involve ACO participants in innovative ways in the ACO's governance or provide Medicare beneficiaries with meaningful representation in the ACO's governance. 42 C.F.R. § 425.106(c)(5).

17. Nonetheless, it remains unclear exactly when CMS will exercise its discretion to waive the 75 percent control and/or beneficiary representation requirements. Although many commentators sought guidance on the use of advisory boards and board committees, CMS did not provide any insight as to whether such mechanisms would be sufficiently innovative to justify a waiver. Further, it remains unclear whether the inclusion of a patient advocate, non-profit association or community representative could adequately represent the views of patients while bringing specific skills and insights to the ACO governing body so as to justify a waiver.

18. 42 C.F.R. § 425.304(a).

19. For instance, the provision of blood pressure monitors to patients with hypertension would be appropriate.

20. The Firm has issued a separate Alert on the waiver rules, which can be accessed at: http://www.bakerdonelson.com/interim-final-waiver-rule-for-acos-11-10-2011/.

21. For instance, the final regulations placed a cap on the overall shared loss rate (i.e., 60 percent of adjusted expenditures benchmark), which, if not corrected, could have resulted in ACOs that achieved 0 quality performance standards being held responsible for 100 percent of any amounts by which actual expenditures exceeded the adjusted expenditures benchmark.