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How CMS's Final Regulations for Accountable Care Organizations Fall Flat

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Abstract: *The Centers for Medicare and Medicaid Services (CMS) has issued final regulations for Accountable Care Organizations (ACOs). The outcome is disappointing: There are marginal changes only; the final regulations retain the same flawed structure set out in the proposed regulations. ACOs remain at the mercy of CMS's determination of their savings target; its calculation will necessarily contain heavy doses of subjective judgment, leaving CMS with great leeway to favor or disfavor ACOs at its discretion. ACOs—whose creation is mandated by the Patient Protection and Affordable Care Act of 2010—will be a strange hybrid of fee-for-service and managed care, subject to ongoing control by CMS. This is a recipe neither for success nor for true accountability.*

The Centers for Medicare and Medicaid Services (CMS) has issued final regulations governing Accountable Care Organizations (ACOs).[1] ACOs are part of the Shared Savings Program—required by the Patient Protection and Affordable Care Act of 2010 (PPACA).[2] The Shared Savings Program is based on the hopeful assumption that if providers join together in ACOs, they can improve the quality and reduce the cost of care for Medicare beneficiaries. ACOs can recover a percentage of the savings they make, in the form of "shared-savings payments" from CMS.

The final regulations maintain the intrusive and baroquely complicated scheme constructed by the originally proposed regulations.[3] While the final rule

Talking Points

- The Centers for Medicare and Medicaid Services (CMS) has issued final regulations governing Accountable Care Organizations (ACOs). ACOs are part of the Shared Savings Program—required by the Patient Protection and Affordable Care Act of 2010 (PPACA).
- The Shared Savings Program assumes that if doctors join ACOs, they can improve the quality and reduce the cost of care for Medicare beneficiaries. ACOs can then recover a percentage of the savings they make, in the form of "shared-savings payments" from CMS.
- ACOs remain responsible for the cost and quality of care provided to their assigned beneficiaries by doctors whom they do not know and cannot control.
- The final CMS regulations change details, yet maintain the intrusive and baroquely complicated scheme constructed by the originally proposed regulations. ACOs are a strange hybrid of fee-for-service and managed care, subject to ongoing and arbitrary control by CMS.

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changes a few details, these do not fix the problems presented by the basic structure of regulatory control that CMS has imposed. It is doubtful that many providers, already skeptical, will be persuaded by these marginal changes to form CMS-sanctioned ACOs.[4]

Hybrid Assignment to ACOs

Under the proposed regulations, CMS would have retrospectively assigned Medicare beneficiaries to ACOs at the end of each year on which the ACOs' annual performance is judged. Such a retrospective assignment meant that ACOs would have been held accountable for the care of beneficiaries provided *before* these beneficiaries had been assigned.

The final regulations are even more bizarre—a hybrid between retrospective and prospective assignment. CMS will make a preliminary assignment of beneficiaries to ACOs at the beginning of the performance year, based on the most recent data available for the preceding 12 months.[5] Quarterly adjustments are made on the basis of the most recent rolling 12-month period.[6] The only assignment that makes any difference in determining the ACO's performance, however, will be retrospective, calculated at the end of the performance year.[7] While a beneficiary may, with or without her knowledge, have been assigned to more than one ACO during the course of the performance year, the ACO to which she is finally and retrospectively assigned at the end of the year is accountable for the cost and quality of her care during the full performance year.[8]

This process, CMS explains, constitutes "preliminary prospective assignment methodology with final retrospective reconciliation."[9] "ACOs will," the preamble of the final regulations says, "be provided with a list of preliminary prospectively assigned set of beneficiaries that would have historically been assigned and who are likely to be assigned to the ACO in future performance years."[10] ACOs will have the option of notifying beneficiaries of the "preliminary prospective assignment and quarterly assignment list."[11] Beneficiaries who receive such a notice will no doubt be puzzled, particularly if they are assigned to different ACOs during the course of the year.

The originally proposed regulations would have assigned a beneficiary to the ACO of the primary care physician who accounted for a plurality of the beneficiary's charges for primary care during the

1. CMS is an agency of the U.S. Department of Health and Human Services. The final regulations were published in the *Federal Register*, Vol. 76 (November 2, 2011), pp. 67802 *et seq.*
2. The PPACA is P.L. 111-148, as amended by P.L. 111-152. The ACO program is created by Section 3022 of the PPACA, which adds a new Section 1899 to the Social Security Act, 42 U.S.C. 1395 *et seq.*
3. John S. Hoff, "Accountable Care Organizations: Obamacare's Magic Bullet Misfires," Heritage Foundation *Backgrounder* No. 2592, August 10, 2011, at *http://www.heritage.org/research/reports/2011/08/accountable-care-organizations-obamacares-magic-bullet-misfires*.
4. The operation of the ACO regulations under the Shared Savings Program is further clouded by the existence of another CMS initiative for ACOs. The Center for Medicare and Medicaid Innovation established its own ACO program—the Pioneer ACO Model—and entered into agreements with 32 Pioneer ACOs. Press release, "Affordable Care Act Helps 32 Health Systems Improve Care for Patients, Saving Up to $1.1 Billion," U.S. Department of Health and Human Services," December 19, 2011, at *http://www.hhs.gov/news/press/2011pres/12/20111219a.html* (January 19, 2012), and Centers for Medicare and Medicaid Services, "Overview," November 21, 2011, at *http://innovations.cms.gov/initiatives/aco/pioneer/* (January 19, 2012).
5. Section 425.400(a)(2)(i) and Section 425.402(a)(1)(i)(A).
6. Section 425.400(a)(2)(ii) and Section 425.402(a)(1)(i)(A).
7. Section 425.400(a)(2)(iii) and Section 425.402(a)(1)(i)(B).
8. Preamble, p. 67864.
9. Preamble, p. 67864.
10. Preamble, p. 67850.
11. Section 425.312(b)(1).

year. The final regulations aggregate all the charges for primary care provided to the beneficiary by primary care doctors in an ACO. If the charges for a beneficiary's care delivered by a particular ACO's primary care providers are greater than those of all primary care providers outside that ACO, the beneficiary is assigned to the ACO with the most charges.[12]

ACO Accountability for Non-ACO Care

The foundational premise of the ACO scheme is that ACOs are accountable for all the care for their assigned beneficiaries. The proposed regulations did not explain how this obligation fits with the right of a beneficiary to consult non-ACO providers. The proposed regulations did not explicitly address whether the ACO is accountable for the cost and quality of care provided by non-ACO doctors—nor do the final regulations. The preamble of the final regulations, however, does address this question: In the context of discussing care received by "snowbirds" (residents of colder climates who reside in Florida during the winter) from providers outside the area of the ACO to which they have been assigned, the preamble states that the ACO is accountable for the care delivered by providers who are not part of the ACO, whether in the same geographical area or not.[13] Judgment on the ACO's quality of care, CMS says, must reflect care provided by non-ACO doctors.[14] Inconsistently, then, in discussing assignment of beneficiaries in different years, CMS states: "We believe that ACOs should not be held accountable for the costs of patients for whom they are no longer to provide primary care due, for example, to a patient moving out of area during a performance year."[15]

CMS Censorship of ACO Communications

CMS insists on approving ACO communications to beneficiaries (ostensibly limited to "marketing materials and activities," but encompassing almost every communication). The final regulation eliminates the proposed requirement that CMS pre-approve ACO communications and replaces it with a file-and-use arrangement.[16] Five business days after submitting them to CMS, an ACO may publish and distribute materials to beneficiaries (if prepared in accordance with any available CMS template) if the ACO "certifies compliance with the applicable marketing requirements" and if CMS does not disapprove the submission during the five-day period. Materials that make it unscathed through the five-day review period are deemed approved, but CMS can un-approve them at any time in the future. ACOs are thus at risk of being found to have made false certifications if CMS claims that the materials do not comply with the regulatory requirements, and their ACO status (and eligibility to earn a Shared Savings Payment) could be terminated. This may cause ACOs to be more cautious in what they say to their beneficiaries than if the materials were subject to CMS pre-approval; prior censorship at least provides certainty. Keeping abreast of changing times, the final regulations include ACO statements made through social media in "marketing materials."[17]

Provider Participation on ACO Governing Board

The proposed regulations would have required that ACO providers exercise proportionate control of the ACO through representation on the govern-

12. Section 425.402(a)(1). The regulations apply a similar rule, based on primary care services provided by specialists in an ACO, for beneficiaries who do not consult a primary care doctor. Section 425.402(a)(2).
13. Preamble, p. 67868.
14. Preamble, p. 67872.
15. Preamble, p. 67864. The Preamble also says that CMS will consider an approach being tested under the ACO Pioneer Model whereby the ACO will not be accountable if the beneficiaries change their Medicare address to, or receive more than 50 percent of their evaluation and management care in, a statistical area that is not adjacent to the area in which the ACO is located. Preamble, p. 67864.
16. Section 425.310.
17. Section 425.20.

ing board. It was difficult to understand how the interest of a single doctor, for instance, would be proportionately represented. The final regulations introduce a more subjective standard: ACO providers must have "meaningful participation in the composition and control" of the governing body.[18] This gives CMS *de facto* control over the composition of the ACO's board.

Many Changes, Few Differences

The final regulations tweak the proposed rules in several ways to slightly reduce the burden on ACOs:

- CMS will fund, or be responsible for, conducting patient experience-of-care surveys in 2012 and 2013. In 2014, these surveys become the responsibility of the ACOs.[19]
- ACOs are given a choice in their first contract period between a one-sided arrangement (they can receive payments for savings but are not responsible for refunding money to CMS if expenditures exceed the target) and a two-sided arrangement (with the possibility of shared-savings payments and payment to CMS for expenditures above the target). Under the proposed regulations, even an ACO that chose the one-sided track would still have been at risk of repayment of losses in the third year of the contract. The final regulations change: An ACO that signs up for the one-sided model is not obligated to return money to CMS if it does not meet its target for the third year. The final regulations maintain the requirement that the second contract period must be a two-sided arrangement.[20]
- The proposed regulations offered various mechanisms to ensure that an ACO pays amounts due CMS as loss recoupment. The final regulations remove one of these mechanisms: CMS will not, as it had previously proposed, withhold 25 percent of any prior shared-savings payments.[21]
- There is a "modest" increase in the limits on the amount of shared-savings payments an ACO can receive; elimination of a 2 percent corridor that an ACO had to exceed before it could receive a shared-savings payment; and an extension of the time an ACO has to repay CMS any amount due as a shared loss.[22]
- The proposed regulations required that the ACO report, and then be judged on its performance, on 65 quality measures. The final rule reduces the number to 33 measures—but with the promise of more in the future.[23]
- The proposed regulations required that at least 50 percent of an ACO's primary care doctors be "meaningful" users of an electronic health record. This requirement is eliminated; in its place, ACOs are "encouraged to develop a robust EHR [electronic health record] infrastructure." CMS will give double weighting to a quality measure that is based on the percentage of primary care doctors who qualify for an EHR-incentive payment.[24]

Conclusion

Except for marginal changes, the final CMS regulations for ACOs retain the structure set out in the proposed regulations.

ACOs are at the mercy of CMS's determination of their savings target; its calculation will necessarily contain heavy doses of subjective judgment, in particular how it makes risk adjustments to reflect the nature of each ACO's assigned population. CMS will have great leeway to favor or disfavor ACOs at its discretion.

ACOs are subject to intrusive regulatory control of every aspect of their management and operation.

18. Section 425.106 (c) and Preamble, p. 67818.
19. Preamble pp. 67835, 67892; and Section 425.500(d).
20. Section 425.600.
21. Preamble, p. 67940.
22. Preamble, pp. 67936–67941; and Section 425.606.
23. Preamble, p. 67891; and Section 425.500.
24. Preamble, p. 67902; and Section 425.506.

In many cases, they remain at risk of being required to make payments to CMS if their costs exceed CMS-imposed targets. They must report to CMS on their use of any shared-savings payments they earn.

Assignment of beneficiaries to ACOs is prospective; revised quarterly; and finally determined on the basis of a retrospective year-end reconciliation. No one knows who is actually assigned to an ACO for purposes of computing savings and determining the quality of the care provided until the relevant year is over. ACOs remain responsible for the cost and quality of care provided to their assigned beneficiaries by doctors whom they do not know and cannot control.

It remains uncertain what incentive ACO providers would have to reduce their Medicare reimbursements. Whether their ACO earns a shared-savings payment depends on the performance of all the providers in the ACO. Even if the ACO is successful, the provider who reduced his Medicare reimbursement would receive a share of the shared-savings payment only at the ACO's discretion—and the amount he receives may well be less than the savings he effected.

ACOs, as described, are a strange hybrid of fee-for-service and managed care, subject to ongoing control by CMS. Like other hybrids, they are not likely to breed naturally. ACOs are a keystone of the PPACA, but they are unlikely to improve health care and reduce its costs. ACOs are further demonstration, if any is needed, that the PPACA is ill-conceived. CMS-directed change will not bring meaningful reform, but impede it.

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