

## AFTERWORD: THE FINAL ACO RULE

*Edward Correia\**

CMS issued its final rule for Accountable Care Organizations (“ACOs”) and the Shared Savings Program (“SSP”) on November 2, 2011.<sup>1</sup> CMS reported that it received over 1,300 comments on its proposed rule and stated that it was “encouraged by the level of engagement by stakeholders.”<sup>2</sup> That is a positive way of describing comments that were overwhelmingly negative.<sup>3</sup> However, CMS gets credit for making a number of revisions in its original proposal in order to make the program more attractive. Whether these modifications are significant enough to make the program successful remains to be seen. There are good reasons to believe that the program still does not offer strong enough incentives to make it attractive to many Health Care Organizations (“HCOs”).<sup>4</sup>

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\* Adjunct Professor, American University Washington College of Law. The author may be contacted at [ecorreia@correiacdc.com](mailto:ecorreia@correiacdc.com).

1. See Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule, 76 Fed. Reg. 67,802 (Nov. 2, 2011) (to be codified at 42 C.F.R. 425).

2. Medicare Shared Savings Program: Accountable Care Organizations; Final Rule, 76 Fed. Reg. at 67,804.

3. For an overview of the proposed rule, including potential problems, some of which have been addressed by the final rule, see Correia, *The Proposed Regulations and Prospects for Success*, 17 AM. J. OF MAN. CARE 31, 37 (2011); see also Douglas Hastings, *The Medicare ACO Proposed Rule: Legal Structure, Governance, and Regulatory Sections*, HEALTHAFFAIRS.ORG (Apr. 5, 2011), <http://healthaffairs.org/blog/2011/04/05/the-medicare-aco-proposed-rule-legal-structure-governance-and-regulatory-sections/>.

4. I use the term HCOs to refer to any health care organization that integrates different types of care, ranging from a simple single hospital-single physician group arrangement to large Integrated Delivery Networks (“IDNs”) that include dozens of hospitals or hundreds of affiliated physicians. As a practical matter, it is likely that only large, highly integrated HCOs can benefit from the ACO program.

*Overview of Changes*

CMS summarized the major changes in the rule as follows:<sup>5</sup>

- (1) greater flexibility in eligibility to participate in the SSP
- (2) multiple start dates in 2012
- (3) establishment of a longer agreement period for those starting in 2012
- (4) greater flexibility in the governance and legal structure of an ACO
- (5) simpler and more streamlined quality performance standards
- (6) adjustments in the financial model to increase financial incentives to participate
- (7) increased sharing caps
- (8) no down-side risk and first-dollar sharing in Track 1
- (9) removal of the 25 percent withhold of shared savings
- (10) greater flexibility in timing for the evaluation of shared savings
- (11) greater flexibility in antitrust review
- (12) greater flexibility in timing for repayment of losses
- (13) additional options for participation of Federal Qualified Health Centers (“FQHCs”) and Rural Health Clinics (“RHCs”).

Of these, the most significant are those that increase the financial incentives to participate in the program—(6) through (9) above, changes in the quality performance standards, revisions in the antitrust review process, and the increased flexibility in governance and legal structure. The comments below focus on these provisions to the original proposal.

*Financial Incentives in the Final Rule*

The central concept of the ACO program is that financial rewards to HCOs can be structured to encourage HCOs to reduce Medicare expenditures for an identified group of beneficiaries while maintaining or improving quality. The trick is to provide those incentives without encouraging HCOs to deny needed benefits and reduce quality of care—the problems that plagued many managed care organizations in the 1970s and 1980s. The ACO program bases these financial rewards on the difference between actual Medicare expenditures and baseline expenditures, which are determined by reviewing the expenditures of the same pool of beneficiaries

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5. See Medicare Shared Savings Program: Accountable Care Organizations; Final Rule, 76 Fed. Reg. at 67,804.

in a previous three year period.<sup>6</sup> This concept is maintained, with a few adjustments, in the final rule.

The proposed rule included a number of limitations on shared savings, which, taken together, significantly reduced the financial attractiveness of the program. The final rule makes a number of changes that eliminate or at least modify these provisions. Financial incentives differ depending on whether an ACO is structured under “Track 1” or “Track 2.”<sup>7</sup> These changes are summarized in the proposed rule.<sup>8</sup> They include the following:

*Eliminating the Shared Loss Provision for “Track 1” ACOs*

The proposed rule provided that ACOs in “Track 1” would share losses beginning in the third year, i.e., if the Medicare expenditures exceeded the benchmark, the ACO would have to reimburse Medicare a portion of the amount by which average costs exceeded the benchmark.<sup>9</sup> This created the risk that an ACO would actually lose money rather than benefit by participating in the program.<sup>10</sup> Under the proposed rule, an ACO could even experience a 100% shared loss rate depending on its quality performance.<sup>11</sup>

The concept of shared losses was retained for ACOs in “Track 2” but the final rule places a cap of 60% on the shared losses.<sup>12</sup> For example, if Medicare expenditures exceeded the benchmark by \$300 per beneficiary, an ACO subject to 60% shared loss rate would have to reimburse CMS \$180 per beneficiary. The final rule also places a cap on shared losses for “Track 2” ACOs of 5% in the first year, 7.5% in the second year and 10% in the third year.<sup>13</sup> For example, if the benchmark is \$10,000 and the ACO’s

6. *Id.* at 67,851.

7. The Track 1 or “one sided” model is the lower-risk, lower-reward model. The Track 2 or “two sided” model provides for higher rewards but also includes the risk of shared losses. *Id.* at 67,904.

8. *Id.* at 67,909-10.

9. *Id.* at 67,937.

10. *Id.*

11. Medicare Shared Savings Program: Accountable Care Organizations; Final Rule, 76 Fed. Reg. at 67,937.

12. *Id.* at 67,909-10.

13. *Id.*

expenditures exceed the benchmark by \$1,000, a 5% cap would mean that the ACO only has to reimburse CMS \$500.

*Shared Savings and the Minimum Savings Rate (“MSR”)*

The original rule provided that, in order to be eligible for any shared savings, ACOs were required to reduce expenditures by a minimum amount below the benchmark. Depending on the number of beneficiaries, the MSR for “Track 1” ACOs ranged from 2.0% to 3.9%.<sup>14</sup> The MSR for “Track 2” ACOs was pegged at a flat 2.0%.<sup>15</sup> The original rule also provided that “Track 2” ACOs could share in savings from the “first dollar” as long as their savings exceeded the 2.0% minimum MSR standard. However, “Track 1” ACOs could share in savings based only on the savings beyond the 2% minimum. A number of commenters argued that this provision made it even more difficult for “Track 1” ACOs to obtain shared savings. The final rule retains the sliding scale MSR for “Track 1” ACOs and the flat 2% MSR for “Track 2” ACOs.<sup>16</sup> However, the final rule allows “Track 1” ACOs to share in first dollar savings, once savings meet or exceed the MSR.<sup>17</sup>

*Shared Savings Rate*

The sharing rate is the percentage of savings that is retained by the ACO. For example, if the average Medicare expenditures by ACO beneficiaries are \$1000 less than the benchmark, and the sharing rate for the ACO is 60%, the ACO is paid \$600 per beneficiary. The proposed rule provided that the maximum shared saving rate for “Track 1” ACOs was 52.5% and 65% for “Track 2” HCOs, if FQHCs or RHCs participated in the ACO. The final rule eliminates this bonus for FQHC and RHC participation and caps the shared savings rate at 50% for “Track 1” HCOs and 60% for “Track 2” ACOs.<sup>18</sup>

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14. *Id.* at 67,927-29.

15. *Id.* at 67,929.

16. *Id.*

17. Medicare Shared Savings Program: Accountable Care Organizations; Final Rule, 76 Fed. Reg. at 67,934.

18. *Id.* at 67,930.

*Eliminating the 25% Withhold*

The proposed rule provided that CMS would withhold 25% of shared savings to ensure that it would be reimbursed for shared losses. This provision meant that ACOs would experience lower reimbursement rates while CMS waited to see if they had to participate in shared losses. This rather draconian provision was eliminated.<sup>19</sup>

*Legal Structure and Governance*

One of CMS's goals in designing the ACO program is to encourage the creation of HCOs that are responsive to the patient population and other constituencies, such as participating providers. Consequently, the proposed rule included a number of provisions regarding the legal structure and governance. Traditionally, large corporations are controlled by a board of directors, chosen by shareholders in the case of for-profit corporations and chosen in some other way, e.g., by the directors themselves, in the case of non-profit corporations. There is no requirement that service providers affiliated with the organization are represented on the board, although they may be. In for-profit corporations, there is traditionally no "proportionality" requirement, except perhaps for those related to equity investments. For-profit corporate governance principles have evolved over a long period and, in theory at least, strike a balance between accountability to shareholders and freedom for directors to exercise sound business judgment. Arguably, requiring a particular form of governance as a condition of participating in the ACO program creates additional barriers to participation and runs the risk that these non-traditional forms of governance may be inefficient and cumbersome.

The final rule dropped some governance requirements but it maintained others. It dropped the requirement that each ACO participant have "proportionate" control over the ACO governing body.<sup>20</sup> This requirement was hard to meet as a practical matter; it also created the risk that certain participants, e.g., physician groups, could dominate the ACO at the expense of other constituencies and overall efficiency. In addition, the final rule dropped a requirement that the ACO require representation on the governing body of particular categories of providers and suppliers.<sup>21</sup> The final rule requires that the ACO provide "meaningful participation in the composition

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19. *Id.* at 67,942.

20. *Id.* at 67,818.

21. *Id.*

and control of the ACO's governing body for ACO participants or their designated representatives."<sup>22</sup> Depending on how it is interpreted, this standard could provide considerable flexibility in creating governance structures, but it also creates the risk that constituencies who do not feel adequately represented will complain to CMS or seek some other remedy. The final rule also maintains a requirement that 75% control of the ACO's governing body must be held by the ACO's participants.<sup>23</sup> Without a proportionate control requirement—which presents its own problem—this 75% requirement could be met by giving a narrow category of participants, e.g., specialty physician groups, 75% of the director seats on the ACO's board. In general, it seems quite possible that CMS's attempt to impose governance rules on ACOs will accomplish little and cause a considerable amount of complexity and conflict within the organizations.

#### *Quality Performance Standards and Shared Savings*

The proposed rule included very demanding quality performance standards in two ways. First, the proposed rule included 65 different standards.<sup>24</sup> Second, CMS proposed that ACOs could receive the maximum shared savings only if they achieved 100% complete and accurate reporting on all quality measures.<sup>25</sup> The combination of this large number of quality measures and the requirement to achieve an acceptable score on all these measures made the quality performance standards very daunting.

Many commenters argued that the large number of standards were confusing and duplicative.<sup>26</sup> The final rule reduces the number of standards to 33.<sup>27</sup> If the patient experience survey requirements, the diabetes-related measures, and the Coronary Artery Disease ("CAD") measures are each counted as one standard, there are only 23 scored quality measures.<sup>28</sup> This

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22. *Id.* at 67,818.

23. Medicare Shared Savings Program: Accountable Care Organizations; Final Rule, 76 Fed. Reg. at 67,821.

24. *Id.* at 67,871.

25. *Id.* at 67,896.

26. *Id.* at 67,802.

27. *Id.* at 67,871.

28. *Id.* at 67,891.

modification simplifies the qualifying performance analysis and makes it easier for ACOs to evaluate and report their performance. In addition, the final rule modifies the minimum performance requirement to 70% of the measures in each of four domains.<sup>29</sup> The minimum attainment level for each measure is 30% of a national standard or the 30th percentile of the Medicare Fee-for-service or Medicare Advantage level of performance.<sup>30</sup>

#### *Antitrust and Marketing Review*

The proposed rule reflected CMS's concern about potential harm to competition if participants in an ACO constituted a large market share of a relevant market. In particular, CMS is concerned that ACOs may reduce competition, particularly in geographic areas, by coordinating the pricing and services of a large percentage of a particular category of providers, such as hospitals or physicians in a particular specialty. In addition, CMS is worried that ACOs might use deceptive marketing materials or market their services so as to attract only low-risk, low-cost beneficiaries. As a result, CMS proposed that certain ACOs would have to undergo an advance antitrust review and that all ACOs would have to submit marketing materials to CMS for advance approval.<sup>31</sup>

It is important to remember that federal and state antitrust laws and consumer protection statutes will continue to apply to the providers in an ACO and to the ACO itself. These advance approval requirements would have had the effect of placing a greater regulatory burden on ACOs than that imposed on other types of businesses that raise an equal or greater risk of harm to competition and consumers. In addition, the advance approval requirements raised the potential for expensive and time-consuming analyses by ACOs as well as the federal agencies required to review their submissions. Consequently, many commenters advocated dropping these mandatory review requirements or least restricting their scope.

The final rule drops the requirement of mandatory reviews altogether and provides for an expedited voluntary review.<sup>32</sup> CMS does promise to work closely with the antitrust agencies to ensure that ACOs do not reduce

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29. Medicare Shared Savings Program: Accountable Care Organizations; Final Rule, 76 Fed. Reg. at 67,898.

30. *Id.* at 67,899.

31. *Id.* at 67,946-47.

32. *Id.* at 67,842.

competition.<sup>33</sup> The final rule also drops the requirement of advance approval of marketing materials.<sup>34</sup> However, the final rule still requires ACOs to submit marketing materials and activities five days before their use.<sup>35</sup> If CMS does not object, these marketing materials and activities are deemed to be approved.<sup>36</sup>

### *Conclusion*

CMS clearly listened to commenters and made a genuine effort to modify the ACO program to make it more attractive. Unfortunately, the final rule is not likely to reduce significantly the structural barriers to the program's effectiveness. Most fundamentally, the financial incentives to the ACO itself and, even more importantly, to individual physicians, are probably too small to make a significant difference in the way large integrated providers operate.

The ACO program is a worthwhile attempt to increase the efficiency of certain HCOs that find the program fits with their particular circumstances. However, it is unlikely, on its own, to "bend the cost curve" or lead to major changes in the way HCOs operate. It is one reform among many that are underway in the health care system as a result of provider efforts as well as cost containment policies by private payers and by CMS itself. These larger trends will play a more significant role in driving the behavior of integrated health care organizations than the ACO program itself.

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33. *Id.*

34. *Id.* at 67,947-48.

35. Medicare Shared Savings Program: Accountable Care Organizations; Final Rule, 76 Fed. Reg. at 67,947.

36. *Id.*