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Provider Participation in ACOs May Hinge on HHS Regulations

BY ROBERT BELFORT

The elusive goal of health reform is to create a reimbursement system that incentivizes medical providers to deliver higher quality care at a lower cost. The recently enacted federal health reform legislation does not establish a single mechanism for achieving this goal. Instead, it authorizes a range of new programs designed to test innovative ways of holding down runaway medical expenses while improving the often uneven quality of care. One of these experiments is the accountable care organization (ACO).[1]

The idea behind ACOs is relatively simple. Rather than keeping doctors and hospitals in their present reimbursement silos, where they are each rewarded largely based on the volume of tests and procedures they perform, ACOs provide a framework for medical providers to work in a coordinated manner across the continuum of care to deliver high-quality, cost-effective services. Under the ACO model, physicians and hospitals both will continue to bill Medicare under the current fee-for-service system.[2] And unlike a managed care organization, they do not have to take any downside financial side risk for the cost of health care services.[3] But if the medical care delivered by the ACO's providers to Medicare beneficiaries meets CMS quality standards and the total cost of this care (including both Part A and B expenditures) is below a predetermined threshold, CMS will share a portion of the cost savings with the ACO.[4]

The opportunity to share in cost savings without taking any downside insurance-type risk is likely to attract the attention of many hospitals and medical groups. But the creation and ongoing operation of an ACO will undoubtedly require substantial clinical, technical and financial resources. As a result, the decision to establish an ACO is by no means free of risk. Prudent health care providers therefore will evaluate the potential risks and rewards of ACOs carefully before making the required three-year commitment to the program.

Providers weighing the decision to create an ACO should have their eyes fixed firmly on the *Federal Register*. For the content of forthcoming HHS regulations implementing the ACO legislation will have an enormous impact on whether the development of an ACO seems like a worthy experiment or a waste of scarce resources. Here are 10 key issues for health care providers to watch in the HHS rulemaking on ACOs.

1. **What methodology will HHS use to risk adjust historical Medicare costs?** The health care reform legislation requires HHS to establish a benchmark of historical per beneficiary Part A and B Medicare costs incurred during the most recent three-year period for which data are available. The benchmark must be adjusted based on the ''characteristics'' of the beneficiary and other factors deemed appropriate by HHS. It must

[1] Patient Protection and Affordable Care Act (PPACA), Section 3022, creating new Section 1899 of the Social Security Act (Section 1899).

[2] Section 1899(d)(1)(A).

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[3] The legislation does authorize the Department of Health and Human Services (HHS) to consider alternative payment models for ACOs such as partial capitation. PPACA § 10307.

[4] Section 1899(d).

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also be updated annually based on the estimated growth in annual Medicare expenditures.[5] The historical cost benchmark is a critical element of the program because it will set the standard against which ACO cost saving efforts will be measured. The extent to which HHS's risk adjustment methodology accurately reflects beneficiaries' health status and other factors relevant to medical costs will be an important consideration for providers contemplating the development of an ACO.

2. **How far below historical Medicare costs will HHS set the cost-saving target?** An ACO will be eligible to receive shared savings payments only if the average Medicare expenditure for the beneficiaries for which it is responsible is ''at least the percent specified by the Secretary below the applicable benchmark . . .''[6] Thus, the legislation suggests that keeping costs below historical levels may not be sufficient; the ACO may have to reduce expenditures by a specified percentage below historical costs to earn shared savings payments. The percentage below historical costs established by HHS obviously will have a major impact on whether providers believe there is a realistic chance of receiving shared savings payments.

3. **What percentage of cost savings below the target will be shared with ACOs?** In addition to setting the per beneficiary expenditure targets, HHS is directed to establish the percentage of savings below the targets that will be shared with the ACO.[7] HHS also is required to set a limit on the total amount of savings that may be passed on to an ACO. The percentage of savings allocated to ACOs and the aggregate cap will define the potential financial upside for ACO sponsors.

4. **Which quality standards will be used by HHS to measure ACO performance?** HHS is given broad authority to establish the quality standards that ACOs must meet to be eligible for shared savings payments.[8] Providers will be focused on whether the standards track existing Medicare pay-for-performance requirements as well as ''meaningful use'' measures linked to the payment of incentives for health information technology adoption. The extent to which providers will have to capture new types of data and develop new types of clinical reports will affect the cost of operating an ACO. In addition, the federal legislation suggests that HHS will ratchet up minimum quality standards over time to promote quality improvement. The manner in which this is accomplished will be an important consideration for providers.

5. **What type of ''patient-centeredness'' criteria will be imposed on ACOs?** The legislation requires ACOs to meet ''patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans.''[9] Given the broad discretion granted to HHS, it is unclear how significantly providers will have to reengineer their systems for interfacing with patients to satisfy the criteria. For example, how different will these criteria be than those established for ''medical homes'' under another Medicare demonstration program? Providers will be looking carefully at whether the criteria require more in depth evaluations of patients, greater accessibility of appointments and consultations, and more intensive ongoing care management than they have provided in the past. They also will be evaluating whether additional staffing and other resources will be needed to meet the criteria.

6. **How will Medicare beneficiaries be assigned to ACOs?** Medicare beneficiaries will be automatically assigned to ACOs. This approach will ease program administration because patients will not have to affirmatively elect to participate in an ACO. But, as a result, providers will not control which patients they assume financial responsibility for. The statute requires HHS to assign beneficiaries to ACOs based on their utilization of primary care services.[10] This means patients assigned to an ACO may utilize high-cost specialists that are not part of the ACO. Based on the nature of the assignment process, providers will have to evaluate how broad their ACO network needs to be to effectively manage the cost and quality of care.

7. **What type of ''formal legal structure'' and ''shared governance'' will be required of ACOs?** The statute requires each ACO to have ''a mechanism for shared governance'' and ''a formal legal structure that would allow the organization to receive and distribute payments for shared savings . . .''[11] HHS could conceivably interpret these provisions as requiring ACOs comprised of multiple legal entities (e.g., a hospital and several medical groups, a hospital and an IPA, etc.) to establish a new joint venture entity to operate the ACO. Alternatively, HHS could permit the ACO's sponsors to create a jointly appointed oversight committee of some type to govern the ACO and channel shared savings payments through one of the sponsors, obviating the need for a new legal entity. The ability to operate within current legal structures may be an important consideration for some providers contemplating the development of an ACO. If a single legal entity is required, this may provide an advantage to integrated health systems with large numbers of employed physicians and previously established joint ventures such as physician-hospital organizations.

8. **To what extent will HHS waive fraud and abuse restrictions for ACOs?** The establishment of any type of joint venture between physicians and hospitals inevitably raises complex legal issues under the federal anti-kickback statute, the Stark law and the civil monetary penalties law. The ACO legislation expressly authorizes HHS to waive the application of these statutes to ACOs.[12] But it is unclear how HHS will exercise this authority. Will new exceptions and safe harbors be created? If so, how broadly will they be crafted? If not, will waivers be granted on a case-by-case basis? Hospitals and physicians will need to be assured that their respective investments in and financial returns from an ACO will be insulated from fraud and abuse scrutiny. In addition, they will be looking for guidance as to whether the many state fraud and abuse laws will be preempted.

9. **Will ACOs be insulated from potential antitrust claims?** One consideration in developing an ACO is whether the new entity might serve as a vehicle for contracting with third party payers other than Medicare. Using an ACO to negotiate with private insurers, how-

[5] Section 1899(d)(1)(B)(ii).
[6] Section 1899(d)(2).
[7] *Id*.
[8] Section 1899(b)(3).
[9] Section 1899(b)(2)(H).
[10] Section 1899(c).
[11] Section 1899(b)(1) and (2)(C).
[12] Section 1899(f).

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ever, potentially implicates antitrust restrictions on price fixing. The Federal Trade Commission has created an antitrust exception for ''clinically integrated'' multi-provider networks that meet certain criteria. If ACOs approved by HHS are deemed clinically integrated for antitrust purposes, they could presumably be used for contracting with private payers. This would likely enhance the incentive to invest the resources in developing an ACO.

10. **How will other state and federal laws be applied to ACOs?** In addition to antitrust and fraud and abuse restrictions, ACO arrangements also may implicate federal tax exemption requirements applicable to hospitals as well as state laws governing fee splitting, the corporate practice of medicine, the certification of physician networks, and similar matters. The extent to which HHS approval of an ACO insulates participating providers from potential claims under these laws is likely to affect both the willingness of providers to participate in ACOs and the way in which ACOs are structured.

Providers contemplating the development of an ACO are subject to conflicting considerations. On the one hand, the lead time necessary to develop the clinical, technological, and organizational structure to operate an ACO by the Jan. 1, 2012, deadline (or perhaps even earlier if HHS accelerates commencement of the program) makes it difficult to defer planning and implementation activities until HHS regulations are issued. On the other hand, it will be hard for providers to assess whether the establishment of an ACO makes sense for them until the questions discussed above have been addressed in the regulations. To balance these competing concerns, providers will have to carefully construct an implementation timeline that balances the need for early planning against the desire to withhold substantial investment until the parameters of the ACO program are clearly fixed.