

Background

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Accountable Care Organizations: Obamacare's Magic Bullet Misfires

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Abstract: *Accountable care organizations (ACOs) are a showpiece of the Patient Protection and Affordable Care Act (PPACA) of 2010. PPACA, known as Obamacare, creates a program in Medicare to stimulate the development of ACOs by making Shared Savings Payments to ACOs if they improve coordination and quality of care and reduce costs. The Obama Administration has published proposed regulations to govern the Shared Savings Program and will issue final regulations before the program goes into effect on January 1, 2012.*

An accountable care organization (ACO), as stipulated by the Patient Protection and Affordable Care Act (PPACA),¹ is a group of doctors and hospitals who join in a separate legal entity that is accountable for the quality and cost of care of all the group's Medicare beneficiaries.² Although this suggests that ACOs are a form of organized care, like health maintenance organizations, they are not. They are more like a vessel for Centers for Medicare and Medicaid Services (CMS) statisticians and health policy gurus to work their craft than a mechanism that actually delivers better care. Expansive rhetoric that ACOs will improve care and reduce costs is based on the assumed incentivizing power of Shared Savings Payments. The actual organizational structure that qualifies as an ACO is muddled.

ACOs: A Microcosm of Obamacare

The ACO scheme is a microcosm of the PPACA and, like it, will not deliver on its rhetorical promises. In the process of failing, it will waste financial and human

Talking Points

- Obamacare uses Medicare reimbursement as an incentive to create accountable care organizations (ACOs), which the federal government has decided are the way to deliver quality care at lower cost.
- Proposed regulations by the Centers for Medicare and Medicaid Services (CMS) are largely confusing, impenetrable, and inconsistent. They give CMS detailed control over ACOs and the providers who participate in them, including censorship of ACO communications with Medicare beneficiaries.
- Medicare beneficiaries are assigned to ACOs without their knowledge or consent. Membership, in reality, is a retrospective book-keeping entry relevant only to financial dealings between CMS and the ACO. ACOs may even have to pay money back to Medicare if they do not meet CMS goals for savings. The incentives offered to ACOs are diffuse and speculative, entailing intrusive regulation of ACOs and providers.
- ACOs as defined by Obamacare are fatally flawed and cannot be fixed by merely changing the proposed regulations.

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resources, detract from meaningful reform, and give the Administration one more tool to exert control over Americans' health care choices.³ Like Obamacare, the ACO program is based on the hubristic assumption that the federal government can design the best organizational structure for the delivery of care, foster its development, and control its operation for the entire country. The federal government has big-footed health system reform. Although there is no one right way to organize care, the federal government thinks it has found one—and exerts top-down, bureaucratic control through PPACA to implement it.

In the name of achieving the worthy goals of better care at lower cost, CMS is given, or has seized, broad regulatory authority.⁴ But aspirational goals and regulatory hammers do not themselves achieve the desired result. The proposed regulations, moreover, are complex and confusing, in some cases downright incomprehensible. In many instances specific provisions are inconsistent with the basic framework of the proposed program. The proposed regulations manage to be at the same time both highly prescriptive and vague. The absence of clear standards gives CMS broad and unchecked discre-

tion to determine how ACOs operate as well as intrusive control over the activities of hospitals and doctors connected to an ACO. Arbitrary actions and favoritism are enabled.⁵

ACO “Participating” Providers...and Other Providers. PPACA defines the categories of providers that may “participate” in the ACO as “ACO professionals in group practice arrangements; networks of individual practices of ACO professionals; partnerships or joint venture arrangements between hospitals and ACO professionals; and hospitals employing ACO professionals.”⁶ This entirely circular definition merely states that an ACO is composed of doctors who participate in the ACO and hospitals that employ them.

PPACA gives CMS authority to add as participants “such other groups of providers of services and suppliers as [CMS] determines appropriate....” The proposed regulations take up that invitation. Without noting that PPACA referred to “groups” of providers and suppliers, the regulations would permit any “provider or supplier” to participate in an ACO.⁷ Any doctor or hospital who “participates” in the Medicare program thus can “participate” in an ACO, whether a member of a group or not.⁸

1. PPACA is P.L. 111–148, as amended by P.L. 111–152. The Shared Savings Program, including ACOs, is created by Section 3022 of PPACA, which adds a new Section 1899 to the Social Security Act, 42 U.S.C. 1395 et seq. The Shared Savings Program is scheduled to go into effect on January 1, 2012. PPACA also sets up a separate program for pediatric accountable care organizations, Section 2706.
2. Social Security Act, Section 1899 (a).
3. For a discussion of the vague and unchecked authority that PPACA gives the Administration to control health care delivery, see John S. Hoff, “Implementing Obamacare: A New Exercise in Old-Fashioned Central Planning,” Heritage Foundation *Background* No. 2459, September 10, 2010, at <http://www.heritage.org/Research/Reports/2010/09/Implementing-Obamacare-A-New-Exercise-in-Old-Fashioned-Central-Planning>.
4. CMS, an agency of the Department of Health and Human Services, published proposed regulations governing ACOs in *Federal Register*, Vol. 76 (April 7, 2011), p. 19528. The proposed regulations are cited by section; statements in the preamble to the proposed regulation are cited by page number of the *Federal Register*.
5. PPACA severely limits administrative and judicial review of CMS decisions under the Shared Savings Program. Social Security Act, Section 1899 (g).
6. Social Security Act, Section 1899 (b)(1).
7. Proposed regulations Section 425.4 and Section 425.5. “Provider” and “supplier” are defined terms under Medicare. A provider is any institutional provider (such as a hospital or skilled-nursing facility) that has an agreement to participate in the Medicare program; a supplier means any physician or other practitioner (such as a physician’s assistant or nurse practitioner) who supplies services under Medicare. 42 CFR, Section 400.202; Social Security Act, Section 1899 (h).
8. The proposed regulations focus on the inclusion of certain specific types of institutional providers, preamble 19537–19539, but do not discuss the fact that they expand the categories of individual participants.

The proposed regulations would also expand the stable of providers involved with ACOs by including providers who are not ACO “participants” but who are referred to as “ACO providers/suppliers”—those who have contracts with ACO participants to provide services and who bill through them, but who have not been granted membership in the ACO club as participants.⁹ Some, but not all, of the requirements imposed on “ACO participants” are applicable also to “ACO providers/suppliers.”¹⁰

The role of the ACO providers/suppliers is often not clear. This is particularly evident in the discussion of the providers to whom the ACO distributes any Shared Savings Payments. In one instance, the proposed regulations specify that an ACO must submit to CMS “the criteria it plans to employ for distributing shared savings among its participants.”¹¹ Elsewhere it refers to distribution of the Shared Savings Payment to encourage “ACO participants *and* ACO providers/suppliers.”¹² (Emphasis added.)

Beneficiaries: Attached to ACOs via Non-Voluntary Retrospective Bookkeeping Entries. Medicare beneficiaries may be surprised to learn that they do not join an ACO as members. Nor is the process voluntary. Strange as it may sound, the CMS “assigns” beneficiaries to an ACO, whether they like or not.

Also odd, the assignment is retrospective. CMS totals each beneficiary’s charges for primary care delivered by ACO primary care doctors during the year and—after the year is over—assigns the beneficiary to the ACO of the primary care doctor who

accounted for a plurality of the charges.¹³ If, during the relevant year, a beneficiary had one visit to an ACO primary care doctor and many visits to another primary care doctor who was not in an ACO, she would retrospectively be assigned to the ACO of the ACO doctor whom she consulted once.¹⁴ The regulations cloak the assignment process as an exercise of beneficiary choice: “CMS determines whether a beneficiary has chosen to receive a sufficient level of the requisite primary care services from primary care physician(s) who is an ACO provider/supplier so that the ACO may be appropriately designated as exercising basic responsibility for that beneficiary’s care.”¹⁵ It is doubtful that beneficiaries will be aware that their pattern of primary care visits will determine their relationship with an ACO. But that is the choice they make in selecting their primary care doctors.¹⁶

Beneficiaries will not know if they have been assigned to an ACO, or, if so, which one. There is no provision for informing beneficiaries that they have been assigned to an ACO. Nor will the ACO have contemporaneous information about either the identity of the beneficiaries who are on its roster or the care they receive. At best it will know who its assigned beneficiaries were after the year is over. During the year in which its performance is judged, the ACO’s information about the beneficiaries for which it is responsible will relate to assumed and aggregated populations.¹⁷

CMS will inform ACOs of the identity only of its “historically assigned beneficiaries” and its “potentially assigned beneficiaries.” It will have (through claims data) concurrent information only about

9. Preamble 19537; proposed regulations Section 425.4.

10. Thus, “ACO participants and ACO providers/suppliers must have a meaningful commitment to the ACO’s clinical integration program. . . .” The ACO must have “policies and procedures for exclusion of ACO participants and ACO provider/suppliers from the ACO.” Proposed regulations: Section 425.5 (d)(9).

11. Proposed regulations: Section 425.5 (d)(11)(i).

12. Proposed regulations: Section 425.5 (d)(9)(ix)(A). See also, Preamble 19545.

13. Proposed regulations: Section 425.6.

14. Social Security Act, Section 1899 (c); proposed regulations: Section 425.6.

15. Proposed regulations: Section 425.4. CMS would prefer to refer to the process as an “alignment,” rather than “assignment.” Preamble 19562.

16. Preamble 19567.

17. Preamble 19554.

care of the aggregate population.¹⁸ The ACO, it appears, will know the identity of its assigned beneficiaries on a contemporaneous basis only to the extent it can extrapolate forward from its “historically assigned” beneficiaries—surely an interesting process. Putting the best light on this situation, CMS states that “Knowing individuals who have been assigned in the past would help the ACO participants to identify individuals who may benefit from improved care coordination strategies going forward.”¹⁹ Or perhaps the ACO will try to extrapolate backwards from its “potentially assigned beneficiaries”—an even more interesting process. The success of what is certain to be a strained effort—if the ACO even bothers to try—is made even more doubtful since there will be substantial change in membership from year to year.²⁰

Contemporaneous identification of its assigned beneficiaries, however, is irrelevant to the ACO. It would not affect how the ACO operates. CMS requires that an ACO—and thus its doctors and hospitals—treat all its Medicare beneficiaries as if they were assigned to it because, as the preamble states, “we do not want to encourage ACOs to limit their care improvement activities to a subset of their patients that they believe may be assigned to

them.”²¹ ACOs are promoted on the hope they will manage the care of their assigned group differently in order to promote quality and efficiency. But if ACO providers must treat all their Medicare beneficiaries as if they were covered by the ACO, then the ACO does not need to know which beneficiaries it was actually assigned. Identification is needed only for CMS’s retroactive calculation to determine the ACO’s performance.

Beneficiaries no doubt will be puzzled by all this. ACO doctors must post signs in their offices and provide written notification to beneficiaries of the doctors’ participation in the Shared Savings Program.²² Beneficiaries might ask what this means to them. The doctor may respond that he does not know if the patient is attached to an ACO but that it really should be of no concern because assignment to an ACO is only a matter of retrospective statistical analysis of the performance of the ACO. The doctor might also assure the patient that all of the ACO’s beneficiaries are treated equally. Americans may be a bit uncomfortable with the complex circularity of this Kafkaesque explanation. CMS promises to develop an outreach program that will explain the ACO program to beneficiaries and inform them that they may be assigned to an ACO for “quality and shared savings purposes.”²³ Not many benefi-

18. The provisions governing which information CMS will release to ACOs about assigned beneficiaries are convoluted. It appears that the import of the various provisions is that CMS will provide ACOs with aggregate data, without individual identification, on the care provided to “historical beneficiaries” and similar aggregate data on beneficiaries “that could potentially be assigned” to it. Proposed regulations: Section 425.19 (b). The ACO can also obtain the names and identification (but not claims data) of the “historically assigned beneficiaries” used to calculate the benchmark. Proposed regulations: Section 425.19 (c). And the ACO can obtain monthly claims data for individually identified “potentially assigned beneficiaries.” Proposed regulations: Section 425.19 (d). The ACO cannot obtain this last category of information unless the beneficiary has been in the office of an ACO primary care doctor during the year, was informed of how the ACO intended to use the information “to improve quality of care” (even though the beneficiary does not know if she has been assigned to the ACO), and the beneficiary did not exercise her right to refuse permission for her information to be shared with the ACO. Proposed regulations: Section 425.19 (d) and (g). Since the beneficiary will be given notice of her right to opt out of data sharing even though she has not been assigned to the ACO, she may find the request somewhat strange.
19. Preamble 19555.
20. CMS points out that there was an annual 25 percent beneficiary turnover in its Physician Group Practice demonstration program. In supporting retrospective, rather than prospective, assignment of beneficiaries to ACOs, CMS nevertheless acknowledges that a 25 percent variability “would not be an accurate reflection” of the beneficiaries seen by an ACO. Preamble 19566.
21. Preamble 19555, 19566.
22. Proposed regulations: Section 425.6 (c).
23. Preamble 19568.

ciaries are likely to understand what this means or find reassurance in it.

Can Beneficiaries Consult Non-ACO Doctors?

But of Course! The proposed regulations emphasize that even though a beneficiary is, unbeknownst to her, retrospectively assigned to an ACO, she is free to consult non-ACO doctors.²⁴ This solicitude for the patient's freedom of choice makes no sense in light of the ACO structure. It is entirely redundant.

The beneficiary is not assigned to an ACO until each year is over. By definition it would be impossible to require her to consult only doctors in an ACO or to impose financial penalties for seeking care outside the ACO to which she has not yet been assigned. At the same time, it is impossible to reconcile the requirement that the ACO is accountable for the overall care of the beneficiaries assigned to it and to coordinate their care with the fact that care will be provided by doctors with whom the ACO has no relationship.²⁵

But CMS Is on the Lookout for ACOs that Avoid Risky Members. Although beneficiaries are free to seek care outside the ACO, CMS appears to be concerned that they might actually do so. PPACA authorizes CMS to impose sanctions if an ACO “has taken steps to avoid patients at risk in order to reduce the likelihood of increasing costs to” it.²⁶ The proposed regulations define “at risk” to include a substantial proportion of Medicare beneficiaries: patients who have had two hospital admissions visits in the year; received a recent diagnosis that is expected to result in increased cost; have a high score in the risk adjustment used to determine the ACO's expected costs; or who are also Medicaid eligible.²⁷ It is assumed that it will be in the ACO's financial interest to “avoid” at-risk patients. But this

concern is illogical and contrary to the structure of the ACO proposal.

Most basically, an ACO cannot “avoid” any patient. Since CMS assigns beneficiaries to the ACO, retroactively, the ACO cannot avoid having the patient included in its roster of beneficiaries.

In any event, at-risk beneficiaries on its roster should not affect the ACO's eligibility for a Shared Savings Payment. The base on which the savings are calculated is adjusted to reflect the expected cost of higher-risk members.²⁸ If the ACO “avoids” a high-risk member, it would have a lower base of expected expenses against which its savings would be judged.²⁹

The regulations do not define what constitutes “avoiding” an at-risk patient. Patients may use ACO participants for some care and consult non-ACO providers on other occasions, as the regulations emphasize is their right. Does that constitute “avoidance” by the ACO? Or does “avoidance” occur only if the ACO refuses to be accountable for the care of the patient—which is impossible since beneficiaries are assigned to the ACO?

This question is particularly apt since the regulations do not explain how the cost of care provided by non-ACO providers is factored into calculation of the ACO's savings, whether or not it is guilty of “avoidance.” If these costs are not added to the ACO's expenditures in calculating whether it is eligible for a Shared Savings Payment, it would have the benefit of a higher-risk adjustment and lower expenditures when the patient goes outside the ACO. The issue arises in all cases, even if the ACO is not guilty of “avoidance.” If, to handle this situation, reimbursement for non-ACO providers is added to the ACO's

24. Proposed regulations: Section 425.6 (a)(2).

25. Preamble 19554.

26. Social Security Act, Section 1899 (d)(3); proposed regulations: Section 425.12; preamble 19625.

27. Proposed regulations: Section 425.4. Preamble 19625 adds to the list of qualifying conditions patients with chronic conditions such as diabetes, coronary artery disease, and depression, as well as two emergency room visits.

28. Social Security Act, Section 1899 (d)(1); proposed regulations: Section 425.7 (b).

29. The preamble implies that by avoiding an at-risk patient, the costs of that patient are not included in the ACO's expenditures. Preamble 19555. But neither would the costs be included in its base of expected expenditures against which actual expenditures are measured.

expenditures, “avoidance” would not present the assumed problem.

Nevertheless, CMS plans to look for “trends and patterns suggestive of avoidance of at-risk beneficiaries.”³⁰ Finding such clues “may subsequently require further investigation and follow-up with the beneficiary or the ACO and its ACO providers/suppliers....”³¹ Presumably the patient will be asked whether the ACO doctor suggested that she consult a non-ACO doctor, and indeed how he phrased his recommendation. CMS will have to probe the doctor’s intent and the patient’s understanding. Beneficiaries may be puzzled by visits from government investigators asking why they exercised their right to seek care outside the ACO to which they could not know they would be assigned.

ACOs Need CMS Approval to Communicate with Beneficiaries. The regulations require CMS approval for ACO communications with Medicare beneficiaries. This censorship applies to “marketing materials or activities” and, more generally, to “all beneficiary communications [including] any materials or activities used by ACO participants or ACO providers/suppliers...to communicate about the ACO in any manner to Medicare beneficiaries.”³² Marketing materials and activities “include, but are not limited to general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages...mailings, or other activities” by which the ACO or a provider or supplier seeks “to educate, solicit, notify or contact Medicare beneficiaries or providers and suppliers regarding the Shared Savings Program.”³³ Not much is missing from this definition, but the preamble does close one gap; it adds telephone calls to the list.³⁴

Exceptions are made for communications to a “customized or limited to a subset of beneficiaries”;

materials that do not provide information about the ACO or its providers; materials that relate to particular beneficiaries’ billing or other specific health related issues; or education information on specific medical conditions.”³⁵ The proposed exceptions appear to come only with the grace of CMS and can be removed by it. CMS will have the power to determine the line between what are exceptions and what are not. ACOs will be reluctant to act unilaterally without its blessings. As a practical matter, therefore, ACOs and their providers may have to put practically everything, written and verbal, through the CMS screen before communicating with beneficiaries.

This overbearing control of ACO communications is ironic, since ACOs do not have to—and indeed cannot—do any marketing; beneficiaries are assigned to them by CMS. CMS claims that its approval of ACO communications is necessary to ensure beneficiaries know that they can obtain care outside the ACO, that they understand that ACOs are not managed care plans, and that doctors do not discourage patients from going to non-ACO providers.³⁶ This concern, of course, is inconsistent with CMS’ other stated concern—that beneficiaries will be encouraged to seek care outside the ACO.

More generally, CMS claims, as government censors typically do, that the control is necessary to “ensure that such communications and marketing by ACOs are used only for appropriate purposes.”³⁷ It offers as the only examples of what is appropriate, notices required by CMS (no doubt its first priority), notices to a beneficiary that a provider is participating in the ACO (required by the regulations), and notices that the ACO or provider is no longer participating in the ACO program (also required by the regulations).

30. Proposed regulations: Section 425.12 (b); preamble 19625.

31. Proposed regulations: Section 425.12 (b). Here, the regulations forget to refer to “ACO participants.”

32. Proposed regulations: Section 425.5 (d)(4) and (5).

33. Proposed regulations: Section 425.4.

34. Preamble 19551.

35. Proposed regulations: Section 425.5 (d)(4).

36. Preamble 19551.

37. *Ibid.*

Shared Savings Payments— and Shared Loss Recoupment

The core of the ACO scheme is that ACOs will have an incentive to improve quality and reduce costs in order to win a Shared Savings Payment. The Shared Savings Payment is based on a series of complex calculations.

CMS estimates the amount that beneficiaries who “would have been” assigned to the ACO in the three previous years would have spent, adjusted for the risk status of the beneficiaries, and updated on the basis of projected “overall growth” in expenditures in the Medicare program.³⁸ This is the benchmark amount. An ACO receives a Shared Savings Payment if Medicare expenditures for its retroactively assigned cadre of beneficiaries are less than the benchmark by more than a threshold amount—if it also meets quality requirements and continues to satisfy all the applicable regulatory requirements.³⁹

CMS proposes 65 quality measures, and promises yet more.⁴⁰ For the first year, the requirement is satisfied by reporting on all of the performance measures. Thereafter, the ACO’s performance will be scored, and it must meet the minimum attainment level to receive a Shared Savings Payment. Performance above the minimum level increases the amount of the Shared Savings Payment on a sliding scale.⁴¹

The amount of a Shared Savings Payment also depends on other factors, such as the number of beneficiaries assigned to it; whether the ACO

is urban or rural; and what kinds of facilities are included in the ACO. It also varies depending on whether the ACO chooses a one-sided or a two-sided arrangement with CMS.⁴²

In a two-sided plan, the ACO is eligible for a Shared Savings Payment, but it must share the losses and pay money to Medicare if its expenditures are greater than CMS projections.

A one-sided arrangement implies that the ACO can win a Shared Savings Payment if it makes the required savings while avoiding the risk of having to refund losses to Medicare if it exceeds its expected expenditures. However, despite its name, the arrangement is one-sided only in the first two years; in the third year it automatically becomes two-sided, and the ACO is at risk of having to pay money to Medicare as if it were under a two-sided arrangement. After the first three-year agreement, only two-sided plans are available.

To ensure that ACOs pay their loss recoupment, CMS withholds 25 percent of any Shared Savings Payments. ACOs also must provide additional protection, satisfactory to CMS, such as surety bonds, escrowed funds, lines of credit, or reinsurance.⁴³ The preamble adds that CMS may recoup Medicare reimbursement paid to ACO participants.⁴⁴ Providers may not be aware that in joining an ACO, they are at risk of being forced to refund their own Medicare reimbursement on the basis of CMS calculations of how much the ACO should have spent and on the performance of their ACO colleagues.

38. Proposed regulations: Section 425.7.

39. Proposed regulations: Section 425.5(a); Section 425.7.

40. Preamble 19594.

41. Social Security Act, Section 1899 (b)(3)(B); proposed regulations: Sections 425.8–.11; preamble 19569–19601.

42. As a general matter, the ACO can obtain a Shared Savings Payment, under the one-sided plan, of as much as 50 percent to 52.5 percent of its savings in excess of 2 percent to 3.9 percent of the benchmark (Minimum Savings Rate), with a cap of 7.5 percent of the benchmark. For the two-sided model, the Shared Savings Payment can be as high as 60 percent to 65 percent of the savings once a similar Minimum Savings Rate is exceeded, with a cap of 10 percent of the benchmark. Proposed regulations: Section 425.7; preamble, Table 8, 19619. Other than in the first two years of its first one-sided arrangement, the ACO must share the “losses” with CMS if its expenditures are greater than its benchmark by more than a threshold amount (Minimum Loss Rate). The loss recoupment is calculated as the inverse of the Shared Savings Payment. Loss recoupment is subject to a cap of 5 percent to 10 percent of the benchmark. Proposed regulations: Section 425.7 (d) (8) and (9).

43. Proposed regulations: Section 425.5 (d)(6).

44. Preamble 19622.

CMS Controls ACOs' Use of Shared Savings Payments. ACOs must tell CMS how they will distribute Shared Savings Payments among their participating providers.⁴⁵ As it concedes, CMS does not have statutory authorization to regulate ACOs' use of Shared Savings Payments they earn.⁴⁶ CMS nevertheless requires ACOs to submit plans documenting that Shared Savings Payments will be used in conformity with CMS criteria. The distribution plan must "achieve the specific goals of the Shared Savings Program" and "achieve the general aims of better care for individuals, better health for populations, and lower growth in expenditures."⁴⁷ The preamble adds more requirements: ACOs must show how the Shared Savings Payment "would be used to promote accountability for their Medicare population and the coordination of their care as well as how they might be invested in infrastructure and redesigned care processes for high quality and efficient health care service delivery."⁴⁸

CMS offers no standards to guide application of its criteria. It does not specify what portion of the Shared Savings Payment it believes should go to infrastructure and redesigned care processes. Nor does it define these terms. CMS will have to sort out whether investments in infrastructure and improved care processes came from the Shared Savings Payment or whether the ACO used other funds available to it—an impossible judgment since money is fungible. CMS can enforce these requirements as it sees fit through its power to approve ACOs and to monitor their compliance. This is another control lever.

CMS Controls Operations of ACOs and Their Providers. CMS cooks up a thick brew of regula-

ry requirements. Failure to meet any one of them to the satisfaction of CMS threatens the ACO's ability to obtain a Shared Savings Payment. The requirements are broad, in most cases without discernible standards; CMS can make up the requirements as it goes along. This unbridled discretion gives CMS ongoing control over the activities of ACOs and their providers. A very small number of the requirements follow, as illustrative examples:

Governance. ACO participants must exercise "shared governance." Each provider who is a "participant" in the ACO must be represented on the governing body and have "appropriate proportionate control" over decision making. At least 75 percent control of the governing board must be held by the "participants."⁴⁹ The most important question is left unanswered: What is proportionate control? Proportionate to what? Is it per capita, or related to the ACO participant's size? Nor do the regulations explain how the participants are to be represented. How, for instance, is the interest, presumably fractional, of a single participating doctor to be calculated and represented? CMS will decide.

The governing body must include one or more Medicare beneficiaries.⁵⁰ It is not clear how this can be done since neither the ACO nor the beneficiaries know which beneficiaries have been assigned to a particular ACO during any given year.

ACOs must have a conflict-of-interest policy requiring members of the governing body to disclose "relevant financial interests" and for the board to address any conflicts.⁵¹ Conflict of interest is an elusive concept when governing board members are explicitly appointed as representatives of the participants. Are the representatives not supposed

45. As described above, the proposed regulations inconsistently require distribution among ACO providers/suppliers as well as ACO participants.

46. Preamble 19544-5.

47. Proposed regulations: Section 425.5 (d)(11).

48. Preamble 19544-5.

49. Social Security Act, Section 1899 (b); proposed regulations: Section 425.4; proposed regulations: Section 425.5 (d)(8).

50. Proposed regulations: Section 425.5 (d)(8); the preamble suggests there need be only one Medicare beneficiary on the board. Preamble 19549.

51. Preamble 19552. Actually, the text of the proposed regulations addressing conflicts of interest is applicable only to the Medicare beneficiaries' representative on the board. Proposed regulations: Section 425.5 (d)(8).

to advance the interests of those they represent?⁵² Is the Medicare beneficiary precluded from objecting to ACO protocols designed to reduce costs on the ground that they compromise care?

Management. ACO management must pass CMS muster. Each ACO must have a chief executive officer, a chief medical officer, and case managers in primary care offices.⁵³ The leadership team must have “demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes.”⁵⁴ Clinical management and oversight must be managed by a board-certified physician. “A physician-directed quality assurance and process improvement committee must oversee an ongoing action-oriented quality assurance and improvement program.”⁵⁵

Operations. ACOs’ operations must satisfy CMS. ACOs must implement “evidence-based medical practice or clinical guidelines and processes.... ACO participants and providers/suppliers must agree to comply with these guidelines and processes and to be subject to performance evaluations and potential remedial actions, including their expulsion from the ACO.”⁵⁶ The ACO must submit documents that describe the “scope and scale of its quality assurance clinical integration program.”⁵⁷

The ACO has to demonstrate that its “leadership and management structure, including clinical and administrative systems...align with and support the goals of the Shared Savings Program and the aims of better care for individuals, better health for populations, and lower growth in expenditures.” ACO providers/suppliers and ACO participants must have a “meaningful commitment to the ACO’s clinical integration program to ensure its likely success.”⁵⁸

One can only wonder what investigations CMS may undertake to explore the validity of this loyalty oath.

An ACO is required to document that it promotes evidence-based medicine, promotes “beneficiary engagement,” and is focused on “patient-centeredness.” This includes: use of a beneficiary care survey to improve care; a process for evaluating the health needs of its assigned population, including consideration of “diversity in its patient populations”; and systems to “identify and update high-risk individuals and processes to develop individualized care plans for targeted patient populations” that are “tailored to the beneficiary’s health and psychosocial needs, account[ing] for beneficiary preferences and values....”⁵⁹

In the same vein, the ACO must have a mechanism “for the coordination of care”; a process for shared decision making that “takes into account the beneficiaries’ unique needs, preferences, values, and priorities”; a process for communicating clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them”; standards for beneficiary access and communication; and processes for measuring clinical or service performance by its physicians.⁶⁰

One of the goals of an ACO is to achieve “better health for populations with respect to educating beneficiaries about the upstream causes of ill health...including...economic disparities.”⁶¹ It is unclear if beneficiaries are to receive this instruction through pamphlets or by doctors’ conversations with them. In either case, they no doubt will be interested to receive this information.

52. The preamble (p. 19552) offers the unhelpful statement that the representatives on the board are “expected to act in the interests of the ACO and Medicare beneficiaries.” If that is the case, why are the board members named as representatives of providers?

53. Proposed regulations: Section 425.5 (d)(9); Preamble 19547.

54. Proposed regulations: Section 425.5 (d)(9); Preamble 19542.

55. Proposed regulations: Section 425.5 (d)(9)(v); Preamble 19542–4.

56. Proposed regulations: Section 425.5 (d)(9).

57. *Ibid.*

58. *Ibid.*

59. Proposed regulations: Section 425.5 (d)(15).

60. *Ibid.*

61. Preamble 19533.

ACOs must submit a “compliance plan” to CMS. The plan must designate a compliance official (who cannot be legal counsel) who can report directly to the ACO governing body. It must state a method for people to “report suspected problems” related to the ACO. Compliance training for the ACO and its providers is required.⁶²

The ACO must establish “partnerships with community stakeholders in order to advance the three-part aim of better care for individuals, better health for populations, and lower growth in expenditures.” It must describe how it “will partner with community stakeholders.”⁶³ Placing a “stakeholder organization” on the ACO’s governing board may satisfy this requirement.⁶⁴

At least 50 percent of the ACO’s primary care physicians must meet the requirement for “meaningful use” of electronic health records by the second year.⁶⁵

Reporting. The ACO must ensure and report on “provider compliance with health care quality criteria” and submit data required under the Physician Quality Reporting System.⁶⁶

The ACO must publicly report its participating providers and suppliers; participants in joint ventures with ACO providers; the names of the members of its governing body and committees; and the names of committee leaders. It must disclose its quality performance scores. And it must report the shared losses it has paid to CMS and the amount of Shared Savings Payments it has received; the proportion that are distributed among the ACO participants; and the “total proportion” used to support quality performance, better care, and lower growth in expenditures.⁶⁷

Each of these regulatory requirements, and the many additional ones like them not discussed here, is an instrument for ongoing CMS control, enforced by the threat of finding instances of non-compliance and disqualifying the ACO from receiving a Shared Savings Payment.

Conclusion: Is the Effort Worth the Payoff?

It is not likely that many groups will try to qualify as ACOs. Providers and integrated care organizations may find that it is not worth the required effort to be eligible for the Shared Savings Payment that is supposed to entice them to enlist.

ACOs’ ability to win a Shared Savings Payment depends on numerous calculations and determinations made by CMS, such as how much an ACO would have spent on its assigned beneficiaries, how the risk profile of that population is adjusted, what it actually spent, and what savings it gained. If the ACO is not successful it does not merely forgo a Shared Savings Payment; it also is at risk of having to pay money back to CMS, and its participating providers may find that their own Medicare reimbursement is subject to recoupment by CMS.

Winning a Shared Savings Payment depends as well on compliance with a host of complex and ambiguous regulatory requirements. This requires extensive and expensive legal, regulatory, and organizational efforts.⁶⁸ In the last analysis, success is measured by how CMS applies its regulations and how it defines compliance with them. Failure to meet the regulatory requirements, as applied by CMS, disqualifies the ACO from receiving a Shared Saving Payment. Compliance with the regulations

62. Proposed regulations: Section 425.5 (d)(10).

63. Proposed regulations: Section 425.5 (d)(3)(v); Section 425.5 (d)(8)(H).

64. Preamble 19551.

65. Proposed regulations: Section 425.11 (b).

66. Proposed regulations: Section 425.11 (a); Section 425.5 (d)(7)(vi).

67. Proposed regulations: Section 425.23.

68. One analyst has suggested, therefore, that larger, more complex organizations have an advantage in qualifying as ACOs, and that the program will increase concentration. See Rita E. Numerof, “Why Accountable Care Organizations Won’t Deliver Better Health Care—and Market Innovation Will,” Heritage Foundation *Background* No. 2546, April 18, 2011, at <http://www.heritage.org/research/reports/2011/04/why-accountable-care-organizations-wont-deliver-better-health-care-and-market-innovation-will>.

subjects the ACO to CMS control over the details of its operations and those of its providers. And if it does receive a Shared Saving Payment, CMS determines how it will be used.

The scheme is of dubious value from the providers' perspective as well. It is not clear that it offers providers an effective incentive to reduce expenditures. The hopeful premise of the plan is that with better coordination of care, more evidence-based medicine, and better use of information technology ACOs can improve the quality of care while constraining growth in Medicare expenditures. But reduced Medicare expenditures mean that some providers in the ACO receive less reimbursement from Medicare than they would have otherwise.

Providers continue to be reimbursed for their services independently of the ACO.⁶⁹ If the providers are reimbursed for a lower amount than CMS estimates they should have been, the benefits of the reductions go to a third party—the ACO—to invest in its own operations and to distribute among its providers. The providers whose reductions in reimbursement accounted for the savings may well find that distributions they receive from the ACO out of the Shared Savings Payment do not equal the amount of their reductions.

The Shared Savings Program, moreover, requires constant cost reductions by the ACO and its providers to avoid paying money to CMS. The ACO may make savings in the first two years of a one-sided agreement, and then find that it does not meet the target in the third year and have to recoup Medicare for the loss. While the benchmark against which its performance will be judged is set for the three years of its agreement, the next agreement begins with a

new benchmark.⁷⁰ It can be expected that CMS will use the level of the ACO's expenditures at the end of its first three-year period as the starting point for the second agreement, increasing the risk that if it re-enlists, it will not be able to continue making savings and will have to pay money back to Medicare.

The Shared Savings Program was modeled on CMS's Physicians Group Practice (PGP) demonstration with 10 large integrated multi-specialty groups. The program was included in the PPACA to reward the groups and offer incentives for other groups to follow their example. CMS assumed that "the 10 physician groups in the PGP demonstration will be uniquely situated and qualified to be among the organizations which are ready to become early participants in the Shared Savings Program."⁷¹ These groups, however, have declined to participate in the program as proposed because of the cost of implementation and the small expected returns.⁷² If the large groups around whom the program was designed conclude that it is not effective, it is unlikely that many other groups will be enticed to go the same route.

In fact, the American Medical Group Association, representing large group practices and integrated health care delivery systems, has informed CMS that 93 percent of its members would not enroll in the Shared Savings Program as structured by the proposed regulations. It concluded that the proposed regulations are too prescriptive and operationally burdensome while offering insufficient incentives.⁷³

CMS's effort, launched by Obamacare, to use the leverage of Medicare reimbursement to impose and control a favored model of health care delivery is bound to fail, but only after increas-

69. Social Security Act, Section 1899 (d); CMS, "Medicare Fact Sheet," March 31, 2011. Social Security Act, Section 1899 (i) authorizes CMS to pay ACOs on a "partial capitation model," but it has not proposed doing so in the pending regulation. Preamble 19534.

70. Social Security Act, Section 1899 (d)(1)(B)(ii).

71. Preamble 19632.

72. Joint letter to Donald Berwick, CMS Administrator, May 12, 2011, at http://www.gastro.org/advocacy-regulation/regulatory-issues/accountable-care-organizations/ACO_Letter_to_the_CMS_From_Ten_Health_Organizations.pdf (July 27, 2011).

73. Letter from Donald W. Fisher to Donald Berwick, May 11, 2011, at <http://www.amga.org/advocacy/MGAC/Letters/05112011.pdf> (July 27, 2011).

ing the angst of providers and patients and dissipating large amounts of resources—money, time, and brainpower. It blocks the development of other ideas for reforming health care delivery. However, changes in the proposed regulations to fix the anomalies and problems discussed above, and numerous other provisions like them not discussed here, would not be sufficient to rescue

the scheme. The Shared Savings Program and its ACOs are fatally flawed by the overweening assumptions embedded in the PPACA itself.

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