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Accountable Care Organizations Proposed Regulations Reveal Significant Financial Opportunities and Structural Requirements

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The proposed regulations with commentary on Accountable Care Organizations ("ACOs")[3] were released by the Department of Health and Human Services ("HHS") on Thursday, March 31, 2011 and provide significant specificity on what Medicare is intending to require and provide for ACOs.[4]

The proposed regulations are 59 pages long; the preamble is 370 pages long.

This article provides a bird's eye view of the proposed regulations and the preamble. ACOs may be up and running by January 1, 2012.

The degree of specificity set forth under the proposed regulations is significant and to be commended. These include specifics on basic physician and minimum patient population requirements, financial rewards and possible loss responsibilities that ACOs must undertake, and dozens of patient care protocols and standards that each ACO will have to adopt. In addition, Medicare intends to specifically review, comment on, and then approve or delay each ACO's separate individual application. The application process is sure to be tedious but the financial rewards can be significant.

1. BASIC REQUIREMENTS REVEALED. The basic requirements for ACO structure and membership are as follows:

A. AT LEAST 5,000 PRIMARY CARE PATIENTS OF ACO PRIMARY CARE PHYSICIANS.

Each ACO will be required to have 5,000 or more primary care Medicare patients, and this will be counted based on the primary care physician Medicare patient population under the ACO.[5]Patients of a specialist who are not "signed on" with one of the ACO's primary care physicians will not be included as ACO patients for the 5,000 patient requirement or financial reward purposes. If at the end of a year the ACO does not have enough patients, there is a one year grace period to correct this. If at the end of the grace period year, the ACO's population has not reached at least 5,000, then the arrangement will be terminated and the ACO will not be eligible to share in savings for that year.[6]

Although 5,000 patients is generally the minimum in order to be in the program, ACOs will want to have more patients because the minimum savings rate that an ACO must achieve in order to receive payments under the program is lower if an ACO has more patients. [7]

It appears possible that an ACO can consist solely of primary care physicians having at least 5,000 patients admitted to the ACO program. The ACO's financial reward calculation will be based on what Medicare pays for all care given to these primary care ACO patients, including services rendered by ACO participants and outside of the ACO. However, from a practical standpoint it will probably be difficult for a successful ACO to consist solely of primary care physicians. This will place a burden on ACO primary care physicians and management to assure optimum management of ACO patient care, whether this occurs under specialists and facilities that specifically participate or do not participate in the ACO.

For purposes of the above patient primary care requirements, the primary care physicians must have a specialty designation of (a) internal medicine, (b) general practice, (c) family practice, or (d) geriatric medicine.[8] While OBGYNs, cardiologists, and pulmonary specialists often act as primary care physicians, they will not be able to do so to qualify patients as ACO patients unless they are double board certified to also act as an internist, family physician, or gerontologist with reference to their relationship with the ACO patient.

Nurse practitioners[9] , physician assistants[10] , and clinical nurse specialists[11] may treat the ACO patients[12], but a primary care medical doctor or osteopath must be considered the patient's "primary care physician" to meet the 5,000 patient test and other applicable requirements.[13] Ownership limitations are not discussed, which would indicate that these non-physicians may have part ownership and economic participation in the ACO.

B. PATIENTS CAN DECIDE TO BE IN OR OUT OF THE ACO.

Each patient will have to be informed of his or her participation in the ACO[14], and will have the right to "opt out" of claims data sharing.[15]

The ACO must supply patients with a form allowing them to opt-out of data sharing.[16] The preamble states that " If the beneficiary objects, we propose that the beneficiary would be given a form stating that they [sic] have been informed of their [sic] physician's participation in the ACO and explaining how to opt-out of having their [sic] personal data shared."[17]

C. SEPARATE LEGAL ENTITY AND OWNERSHIP REQUIREMENTS.

The Regulations indicate that the ACO shall be a separately formed legal entity[18], which can be a limited liability company, a professional corporation or other entity.

The ACO will have a separate taxpayer identification number that will be linked on Medicare records with the identification numbers of all ACO participants .[19] The organization will have to have bylaws or equivalent documentation to show appropriate ownership and governance.[20]

The following ACO participants are eligible, separately or in combination, to form ACOs[21]:

1. ACO professionals, including physicians and nurse practitioners, in group practice arrangements.[22]
2. Networks of individual practices of ACO professionals.
3. Partnerships or joint venture arrangements between hospitals and ACO professionals.

4. Hospitals employing ACO professionals.
5. Providers or suppliers as defined under § 425.4.[23]
6. Critical Access Hospitals ("CAH") as described in § 413.70(b)(3).[24]

D. CONTROL REQUIREMENTS.

At least 75 percent of control of an ACO's governing body must be held by ACO participants.[25]ACO participants are described in the six categories in Section C. above.

At least one Medicare ACO system patient must sit on the governing board.[26]Ownership limitations are not discussed, which would indicate that any combination of ownership will be satisfactory if appropriately registered and legal in the state of operation.

For example, hospitals and specialist groups may fund ACOs in exchange for rights of participation and percentages of profits. Primary care physicians may be given ownership and rights to a percentage of profit in exchange for being willing and able to participate in the ACO and to bring significant portions of their patient bases in for participation. Profits may be allocated among primary care physicians and specialists in recognition of how their ACO patient expenses compare to those of others in the ACO.

2. COLLABORATION WITH OIG, FTC, DOJ and IRS.

In what might be unprecedented inter-agency collaboration, the CMS along with OIG, FTC, DOJ and the IRS also proposed additional rules to work in tandem with the proposed regulations. This shows how determined the government is to make these work.

3. CONCLUSION.

The proposed regulations and joint CMS/OIG notice are posted at http://www.cms.gov/sharedsavingsprogram.

Comments on the proposed regulations will be accepted until June 6, 2011. Before the regulations are finalized, CMS will review all comments from the public and may make changes to its proposals based on those comments.

The Proposed Antitrust Policy Statement is posted at: www.ftc.gov/opp/aco/.

The IRS Guidance and Solicitation of Comments is posted at: http://www.irs.gov/pub/irs-drop/n-11-20.pdf.

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3 Section 3022 of the Affordable Care Act.

4 The Patient Protection and Affordable Care Act was enacted on March 23, 2010 and the Health Care and Education Reconciliation Act of 2010 was enacted on March 30, 2010. These laws are collectively known as the Affordable Care Act. Section 3022 of the Affordable Care Act requires the establishment of the Medicare Shared Savings Program, which is intended to encourage the development of Accountable Care Organizations.

5 Section 425.5(d)(13).

6 Section 425.5(d)(13) states "(i) CMS will deem an ACO to have a sufficient number of primary care physicians and beneficiaries if the number of beneficiaries historically assigned to the ACO participants using the assignment methodology in §425.6 is 5,000 or more. (ii) If at the end of a performance year, an ACO's assigned population falls below 5,000, then that ACO will be issued a warning and placed on a CAP. (A) While under the CAP, an ACO remains eligible for shared savings and losses during that performance year. (B) If the ACO's assigned population has not returned to at least 5,000 by the end of the next performance year, then that ACO's agreement will be terminated and the ACO will not be eligible to share in savings for that year."

7 Section 425.7(c)(2).

8 Section 425.4.

9 42 C.F.R. 410.75(b) defines a nurse practitioner as "(1)(i) Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law; and (ii) Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; or (2) Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law and have been granted a Medicare billing number as a nurse practitioner by December 31, 2000; or (3) Be a nurse practitioner who on or after January 1, 2001, applies for a Medicare billing number for the first time and meets the standards for nurse practitioners in paragraphs (b)(1)(i) and (b)(1)(ii) of this section; or (4) Be a nurse practitioner who on or after January 1, 2003, applies for a Medicare billing number for the first time and possesses a master's degree in nursing and meets the standards for nurse practitioners in paragraphs (b)(1)(i) and (b)(1)(ii) of this section."

10 42 C.F.R. 410.74(a)(2) defines a physician assistant as "(i) Meets the qualifications set forth in paragraph (c) of this section; (ii) Is legally authorized to perform the services in the State in which they are performed; (iii) Performs services that are not otherwise precluded from coverage because of a statutory exclusion; (iv) Performs the services under the general supervision of a physician (The supervising physician need not be physically present when the physician assistant is performing the services unless required by State law; however, the supervising physician must be immediately available to the physician assistant for consultation.); (v) Furnishes services that are billed by the employer of a physician assistant; and (vi) Performs the services—(A) In all settings in either rural and urban areas; or (B) As an assistant at surgery."

11 42 C.F.R. 410.76(b) defines a clinical nurse specialist as "(1) Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to perform the services of a clinical nurse specialist in accordance with State law; (2) Have a master's degree in a defined clinical area of nursing from an accredited educational institution; and (3) Be certified as a clinical nurse specialist by a national certifying body that has established standards for clinical nurse specialists and that is approved by the Secretary."

12 Section 425.4.

13 Section 425.5(d)(13)(i).

14 Section 425.5(d)(5)(i).

15 Section 425.12 (e).

16 Section 425.19(g)(2).

17 Section II.C.6.b. of the Preamble.

18 Section 425.5(d)(7).

19 Section 425.5(c).

20 Section 425.5(d)(9)(ix)(F).

21 Section 425.5(b).

22 Section 425.4 defines "ACO professional" as either "(1) A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action, including an osteopathic practitioner within the scope of his or her practice as defined by State law, [or] (2) A practitioner who is one of the following: (i) A physician assistant (as defined by § 410.74(a)(2)), (ii) A nurse practitioner (as defined at § 410.75(b)), (iii) A clinical nurse specialist (as defined by § 410.76(b))." See endnotes x, ix, and xi above for the definition of "physician assistant", "nurse practitioner" and "clinical nurse specialist"

23 Section 425.4 defines "provider" as defined in § 400.202. 42 C.F.R. 400.202 defines a "provider" as "a hospital, a CAH, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services." Section 425.4 defines "supplier" as defined in § 400.202 "that bills for items and services it furnishes to Medicare beneficiaries under a Medicare billing number assigned to the to the TIN of an ACO participant in accordance with applicable Medicare rules and regulations." 42 C.F.R. 400.202

defines a "supplier" as "a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare."

24 42 C.F.R. 413.70(b)(3) states "(i) A CAH may elect to be paid for outpatient services in any cost reporting period beginning on or after July 1, 2004 under the method described in paragraphs (b)(3)(ii) and (b)(3)(iii) of this section... (ii) If the CAH elects payment under this method, payment to the CAH for each outpatient visit will be the sum of the following: (A) For facility services not including any services for which payment may be made under paragraph (b)(3)(ii)(B) of this section, 101 percent of the reasonable costs of the services as determined under paragraph (b)(2)(i) of this section; and (B) For professional services that are furnished by a physician or other practitioner who has reassigned his or her rights to bill for those services to the CAH in accordance with Part 424, Subpart F of this chapter, and that would otherwise be payable to the physician or other practitioner if the rights to bill for them had not been reassigned, 115 percent of the amounts that otherwise would be paid for the service if the CAH had not elected payment under this method. (iii) Payment to a CAH, other than for clinical diagnostic laboratory tests, is subject to the Part B deductible and coinsurance amounts, as determined under §§410.152(k), 410.160, and 410.161 of this chapter."

25 Section 425.5(d)(8)(iv).

26 Section 425.5(d)(8)(ii).
