Key Risk Management Issues with Accountable Care Organizations

PASHRM Spring Conference 2012

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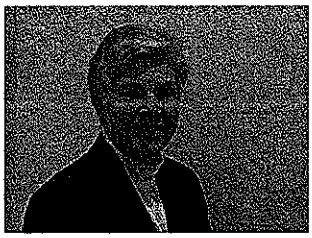

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Ms. Rozovsky has lectured extensively and authored or co-authored over five hundred articles and several books including *Consent to Treatment: A Practical Guide, What Do I Say? Communicating Intended or Unanticipated Outcomes in Obstetrics* (with Dr. James R. Woods), *The Handbook of Patient Safety Compliance* (co-edited with Dr. James R. Woods) and most recently, *Health Care Organizations Risk Management: Forms, Checklists and Guidelines*, Third Edition (with Jane L. Conley).

A summa cum laude graduate of Providence College, Ms. Rozovsky received her J.D. from Boston College Law School and an M.P.H. from the Harvard School of Public Health. Ms. Rozovsky is admitted to the practice of law in Florida and Massachusetts.

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Acronym List:

ACO	Accountable Care Organization
AHRQ	Agency for Healthcare Research and Quality
CAP	Corrective Action Plan
DOJ	Department of Justice (U.S.)
DUA	Data User Agreement
EHR	Electronic Health Record
ERM	Enterprise Risk Management
FTC	Federal Trade Commission
FQHC	Federally Qualified Health Clinic
HIE	Health Information Exchange
IOM	Institute of Medicine
IRS	Internal Revenue Service
ISO	International Standards Organization
NCQA	National Committee on Quality Assurance
NQF	National Quality Forum
OIG	Office of the Inspector General (HHS)
PCE	Potential Compensatory Event
RHC	Rural Health Clinic
TIN	Tax Identification Number

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Suggested Readings:

American Hospital Association, "Accountable Care Organizations: Guidance to Address Antitrust, Fraud & Abuse and Tax Exemption Barriers," Legal Advisory, November 8, 2011.

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R. Carroll Editor, RISK MANAGEMENT HANDBOOK FOR HEALTHCARE ORGANIZATIONS, SIXTH EDITION. San Francisco: Jossey-Bass, 2011.

National Committee on Quality Assurance, "Accountable Care Organization Accreditation Standards," www.ncqa.org/tablid/1312/Default.aspx.

F.A. Rozovsky and J.L. Conley, HEALTH CARE ORGANIZATIONS RISK MANAGEMENT: FORMS, CHECKLISTS, AND GUIDELINES, THIRD EDITION. New York: Aspen Publishers, 2009 (with annual supplements).

F.A. Rozovsky, C. W. Giles, and M. A. Kadzielski, HEALTH CARE CREDENTIALING: A GUIDE TO INNOVATIVE PRACTICES. New York: Aspen Publishers, 2007 (with annual supplements).

The Patient Protection and Affordable Care Act, Pub. L. No. 111-48, 124 Stat. 1029 (2010).

The Health Care and Education Reconciliation Act of 2010, Publ. L. No. 111-52, 124 Stat. 1029 (2010).

U.S. Department of Justice & Federal Trade Commission, "Statements of Antitrust Enforcement Policy in Health Care, Statements 8 and 9," (1996) accessible at: http://www.ftc.gov/reports/hlth3s.pdf.

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Federal Materials:

Federal Trade Commission and U.S. Department of Justice, Antitrust Division, "Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program," Final Policy Statement, October 20, 2011.
www.justice.gov/atr/public/health_care/276458.pdf

Internal Revenue Service, "Tax-Exempt Organizations Participating in the Medicare Shared Savings Program through Accountable Care Organizations," IRS Fact Sheet FS-2011-11, October 20, 2011.

"Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations," Final Rule, Federal Register 76(212): 67802- 67990, November 2, 2011.

"Medicare Program Advanced Payment Model," Notice, Federal Register 76(212): 68012, November 2, 2012.

Medicare Program; Final Waivers in Connection With the Shared Savings Program, Interim Final Rule with comment period, Federal Register 76(212): 67992-68010, et seq, November 2, 2011.

U.S. Department of Justice & Federal Trade Commission, "Statements of Antitrust Enforcement Policy in Health Care, Statements 8 and 9," (1996) accessible at: http://www.ftc.gov/reports/hlth3s.pdf.

THE ROZOVSKY GROUP, INC.
RMS RISK MANAGEMENT SERVICES NEWSLETTER

Volume Seven - Number Three March 2011

Conflict of Interest and ACOs

Accountable Care Organizations or "ACOs" are the buzz in the healthcare industry. Similar models have been in existence for some time. The Medicare ACO is a creation of the Shared Savings Program component of the voluminous health reform law, PPACA, signed into law in March, 2010.

The Shared Savings Program is set to take effect in January, 2012. Proposed regulations to implement the law were released on March 31, 2011 in a pre-publication format with the anticipated formal version in the April 7, 2011 edition of the Federal Register.[1]

Along with the ACO proposed rule, several documents were released by the Office of Inspector General of HHS and CMS[2], the FTC and DOJ,[3] and the IRS.[4]

There will be a sixty-day comment period for the ACO regulation. In the interim, there will be experts in a variety of health law and health care disciplines digesting the content with a view to providing commentary to inform CMS on the final rule.

Looking at the ACO concept, there are a host of concerns, from sharing risk of loss in revenue to matters involving consent, credentialing, and cyber security. One issue that merits closely scrutiny is conflict of interest. Issues involving conflict of interest could trigger director and officer (D&O) and other types of risk exposure.

To better understand this emerging risk exposure, it is useful to explain what is included in the ACO concept. Situations of apparent conflict of interest can be hypothesized with a view to preventing and managing such risk exposure.

The Medicare ACO Concept.

Section 3022 of the Patient Protection and Affordable Care Act requires the Secretary of Health and Human Services to establish the Medicare Shared Savings Program ("Shared Savings Program"), which, in turn, is intended to encourage the development in Medicare of Accountable Care Organizations or ACOs.[5]

A number of reforms can be found in the voluminous law geared to giving shape to the Shared Savings Program. The Shared Savings Program adds a new section – 1899 – to the Social Security Act.[6]

In the proposed rule, CMS referred to these reforms as the "three-part" aim of

> "(1) better care for individuals; (2) better health for populations; and (3) lower growth in expenditures..."[7]

Through changes in infrastructure and process redesign, the law envisages that:

> "groups of providers of services and suppliers meeting criteria specified by the Secretary may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an [ACO]". Section 1899(a)(1)(B) of the Act also provides that ACOs that meet quality performance standards established by the Secretary are eligible to receive payments for "shared savings".[8]

In the Medicare version of the ACO, the following providers of both services and suppliers may participate in an Accountable Care Organization:

> "• ACO Professionals in group practice arrangements.
> • Networks of individual practices of ACO professionals.
> • Partnerships or joint venture arrangements between hospitals and ACO professionals.
> • Hospitals employing ACO professionals.
> • Such other groups of providers of services and suppliers as the Secretary determines appropriate."[9]

Section 1899(b)(2) of the Act also sets a number of eligibility requirements. These include that:

"• The ACO shall be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service (FFS) beneficiaries assigned to it.
- The ACO shall enter into an agreement with the Secretary to participate in the program for not less than a 3-year period.
- The ACO shall have a formal legal structure that would allow the organization to receive and distribute payments for shared savings to participating providers of services and suppliers.
- The ACO shall include primary care ACO professionals that are sufficient for the number of Medicare FFS beneficiaries assigned to the ACO. At a minimum, the ACO shall have at least 5,000 such beneficiaries assigned to it in order to be eligible to participate in the Shared Savings Program.
- The ACO shall provide the Secretary with such information regarding ACO professionals participating in the ACO as the Secretary determines necessary to support the assignment of Medicare fee-for-service beneficiaries to an ACO, the implementation of quality and other reporting requirements, and the determination of payments for shared savings.
- The ACO shall have in place a leadership and management structure that includes clinical and administrative systems.
- The ACO shall define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.
- The ACO shall demonstrate to the Secretary that it meets patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans."[10] [Emphasis added]

There are other considerations that will determine the legal-regulatory success of Medicare ACOs. As noted earlier, input from the IRS, DOJ, the Inspector General of HHS, and the FTC will be part of the framework for ACOs.

No doubt the proposed regulations will undergo some modification by the time the Final Rule is promulgated and guidance firms up from other regulatory entities. When the dust settles, the healthcare field will know what to expect in terms of the treatment of tax-exempt healthcare organizations participating in ACOs under IRS requirements. Similarly, there will be a better understanding of possible waivers under the Physician Self-Referral Law, the Federal anti-

kickback statute, and some of the civil monetary penalties (CMP) provisions for certain financial arrangements involving accountable care organizations. An interesting prospect is the wavier of fraud and abuse laws when testing innovative payment and service delivery models by the Center for Medicare and Medicaid Innovation under the Shared Savings Program. Last, but by no means least, is what the Federal Trade Commission has labeled the FTC Antitrust "Safety Zone."[11]

Lawyers, compliance experts, and tax advisors are apt to have a busy period trying to assist healthcare clients develop acceptable Medicare ACOs. They will help clients decide whether the legal structure is a corporation, partnership, a joint venture or an LLC. They will help them determine who will provide management, leadership and governance of the ACO. All and all, it is a topic ripe for engagement of risk management professionals throughout the design and implementation processes.

Conflict of Interest – Prime Time for Risk Management.

One aspect of ACOs that can and should be addressed early on is the issue of conflict of interest. The topic is of such importance to CMS that in the proposed regulation, a subsection of the Preamble was devoted to the subject.[12] Moreover, conflict of interest is also part of the definition of "Shared Governance."[13]

Is it possible that one component of the ACO could dominate another in the decision-making process? Is it possible that the motivation is self-interest on the part of the dominant player to guard against choices that maximize potential shared savings to the detriment of Medicare beneficiaries? Is it possible that members of the governing body of the ACO may have an inherent conflict of interest?

These are not matters of idle speculation. Consider what CMS said on the topic:

> "We are proposing that the ACO governing body have a conflicts of interest policy that applies to members of the governing body. The purpose of this proposal is to ensure that members of the governing body act in the best interests of the ACO and Medicare beneficiaries. We propose that the conflicts of interest policy must require members of the governing body to disclose relevant financial interests. Further, the policy

> must provide a procedure for the ACO to determine whether a conflict of interest exists and set forth a process to address any conflicts that arise. Such a policy would also address remedial action for members of the governing body that fail to comply with the policy. We solicit comments on this proposal, including the scope and content of such a policy."[14] [Emphasis added]

Earlier in the Proposed Rule, CMS introduced the idea of a Medicare beneficiary becoming a member of the governing body of the ACO. The idea would be that the presence and input of the Medicare beneficiary would help promote outcomes that are aligned with the goals of the Shared Savings Program and patient-centered care. In essence, having a recipient participate in governance could help the ACO stay the course.

Even for the Medicare beneficiary, CMS posited the need to address conflict of interest:

> "In order to safeguard against any conflicts of interest, any patient(s) included in an ACO's governing body, or an immediate family member, must not have any conflict of interest, and they may not be an ACO provider/supplier within the ACO's network."[15]

It is laudable that CMS recognized the inherent conflict of interest that may reside in an ACO. In a subsequent section, CMS described the need for screening of ACO applicants.[16] Although CMS did not use the term "credentialing," the screening process might involve such activity. This will be important, especially if would-be provider participants are denied entry or removed from the ACO on grounds tantamount to economic credentialing rather than quality of care issues.

So what might be the risk exposures with ACOs and conflict of interest? There are several potential issues. These include:

Wrongful denial of providers from the ACO – might it result in a deviation from the FTC Antitrust "Safety Zone" and thereby create a potential for litigation under antitrust laws?

Wrongful debarment from the ACO – taking action to delist or remove a provider or provider group on the grounds that they are not "saving" enough funding while meeting evidence-based clinical care guidelines and promoting high quality, patient-centered care. Might there be litigation based on breach of contract, or

bylaws? Might there be a risk exposure for director and officer liability if the governing body permits such action resulting in disruption of quality care for patients?

Wrongful economic credentialing – if the selection and screening process used by the ACO is a credentialing model, might the ACO be subject to wrongful economic credentialing, particularly when the care providers are achieving high scores on quality, patient-centered care?

Negligent credentialing – could there be more than a Director and Officer's liability exposure, particularly if the screening and selection process built into the credentialing system is skewed so that "friendly" providers are selected whose quality indicators are suspect? Might there be a negligent credentialing exposure if the ACO knew or *ought to have known* that the providers selected did not meet established criteria, and as a reasonably foreseeable consequence, Medicare beneficiaries were injured? In such a circumstance, the plaintiff might argue that the inherent conflict of interest deterred the ACO from meeting established standards for credentialing providers in the Shared Savings Program accountable care organization.

Lack of informed consent - is there a duty on the part of the ACO and providers to disclose to Medicare beneficiaries the potential financial reward healthcare professionals might realize by taking part in the accountable care organization? If the patient did not know about the involvement in the ACO and how it might influence the clinical decision-making of the care provider, might there be a basis for claim for lack of informed decision-making? Such a claim might be based in part on the idea that the patient was denied information that a reasonable person in a similar circumstance would want to know so that he or she could decide whether to seek care from a non-ACO provider. In essence the financial conflict of interest might have hampered the informed consent process.

One could go on and identify other risk exposures involving some aspect of conflict of interest. The point is that ACO conflict of interest risk exposures merit careful analysis and action.

Strategies to Address ACO Conflict of Interest Issues.

It is noteworthy that there are good models in the literature on conflict of interest.[17] A strong conflicts of interest policy is important, too. There are a number of practical strategies to consider, including the following:

1. **Develop a Clear Conflict of Interest Policy for the ACO.**
   Review current models in the healthcare field for conflict of interest.[18] Consider models from other industries that must guard against financial conflict of interest. Use these models to help design an ACO-appropriate conflict-of-interest policy. Utilize a team of content experts to frame the conflict of interest policy.

2. **Provide Orientation Programs for ACO Governance and Leadership.**
   Make mandatory a conflict of interest education program for those responsible for governance and leadership. Consider using case studies to evaluate understanding and application of the conflict of interest policy. Maintain a log of the date, time, and location of such programs as well as the names and positions of attendees. Recognize that this may become useful information in situations in which there are assertions made that the governing body or leadership lacked training on conflict of interest.

3. **Consider Conflict of Interest Credentialing.**
   Think about implementing a conflict of interest credentialing process.[19] Consider such a concept in the recruitment of those in governance, leadership and in screening care providers for the ACO.

4. **Build into the Bylaws Provisions that Address Conflict of Interest.**
   Address the issue of conflict of interest in the bylaws of the ACO to make certain that this governing document sets the framework for handling such matters.

5. **Build into Contracts Language that Addresses Conflict of Interest.**
   Work with legal counsel to define conflict of interest for contracts issued by the ACO. Include in the contract mechanisms to address conflict of interest, including the ability to "cure" such situations or to terminate the contract.

6. **Make Certain Credentialing Committees Receive Conflict of Interest Training.**
   Provide training for those responsible for recruitment and credentialing on conflict of interest, especially with respect to inappropriate use of economic credentialing and individual favoritism. Stress the importance of following credentialing criteria that is aligned with the Shared Savings Program's three aims.

7. **Consider an Ethics Officer or Committee Process for Conflict of Interest.**
   Discuss with governance and leadership the prospect of using an ethics advisor or officer or a committee to handle conflict of interest issues. Recognize that such an individual or committee may have a background in business and/or healthcare ethics.

8. **Institute an Internal Review Process to Identify Conflict of Interest Matters.**
   Develop a framework for identifying conflict of interest situations. Include in such an identification process clinical, transactional, contractual, and coding and billing activities.

9. **Institute a Process to Address Conflict of Interest Situations.**
   Make certain that the conflict of interest process includes a prompt, thorough and fair investigation, and resolution, of identified conflict of interest situations. Document the rationale for and disposition of such matters.

10. **Consider Insurance Requirements.**
    Work with an insurance agent or broker to evaluate the insurance portfolio for participation in an ACO. Look for coverage for conflict of interest for those representing a physician practice, hospital or another provider entity in the leadership or governance of the ACO. Recognize that the coverages in place for the individual entities may not encompass membership, ownership, or partnership in an ACO. Think about the insurance requirements for other aspects of the ACO, including D&O, E&O, cyber risk and stop loss coverage. Complete a similar analysis for those with insurance captives.

Conclusion.

In theory, the ACO is a fairly straightforward concept. However, the mosaic of legal and regulatory requirements that impact the accountable care organization is apt to make the ACO the subject of complex legal and financial analysis.

For healthcare risk managers, the ACO may serve as the business case for enterprise risk management. The ACO will impact all aspects of a healthcare organization whether a contractual entity, or a physician group that becomes

immersed in a limited liability company, joint venture or another legal framework for an accountable care organization.

There are many weeks ahead in which national organizations and individuals will review the ACO proposed rule and the other regulatory documents. The regulatory authorities anticipate a watershed of comments and suggestions. This should include healthcare risk management professionals.

For now, it is a good time for risk management professionals to help leadership evaluate the ACO options, utilizing the practical tools found in enterprise risk management. Conflict of interest matters may usher in a broader, enterprise-wide assessment prior to participating in an ACO.

If you would like assistance with a risk management plan or education please contact us at (860) 242-1302.

[1] Medicare Shared Savings Program: Accountable Care Organizations, CMS, HHS, Proposed Rule. March 31, 2011, Accessed at http://www.ofr.gov/OFRUpload/OFRData/2011-07880_PI.pdf.

[2] Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center, CMS, OIG, and HHS, Notice with commentary period March 31, 2011. Accessed at: http://www.ofr.gov/OFRUpload/OFRData/2011-07884_PI.pdf

[3] FTC, DOJ Seek Public Comment on Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Provides for Antitrust "Safety Zone" and Expedited Antitrust Review, March 31. 2011. Accessed at: http://www.ftc.gov/opa/2011/03/aco.shtm.

[4] IRS, NOTICE 2011-20, March 31, 2011. http://www.irs.gov/pub/irs-drop/n-11-20.pdf

[5] PPACA, Pub L. 111-148 (March 23, 2010).

[6] See, 42 U.S.C. 1395 et seq.

[7] Medicare Program; Medicare Shared Savings Program, supra note 1 at p. 15.

[8] Id.

[9] Id., at 15-16.

[10] Id., at 16-17.

[11] See references 1-4, supra.

[12] Id., at p. 101.

[13] Id. at p. 383.

[14] Id., at p. 101.

[15] Id. at p 90.

[16] Id. at pp. 101-102.

[17] See. for example, F.A. Rozovsky, C.W. Giles and M. A. Kadzielski, HEALTH CARE CREDENTIALING: A GUIDE TO INNOVATIVE PRACTICES. New York: Aspen Publishers, 2007 with annual supplements.

[18] See, These include policies developed by the Association of American Medical Colleges (AAMC) [AAMC –AAU Advisory Committee on Financial Conflicts of Interest in Human Subject Research, February, 2008]and the American Medical Association [PHYSICIAN'S GUIDE TO MEDICAL STAFF ORGANIZATION BYLAWS , FOURTH EDITION, 2007.]

[19] See. HEALTH CARE CREDENTIALING: A GUIDE TO INNOVATIVE PRACTICES.. supra note 17.