It is impossible to pick up a health care journal and not read about someone touting the benefits which Accountable Care Organizations (ACOs) will bring to our health care delivery system. But really what do you know about ACOs, how will they operate, and what, if any benefits will they achieve? As a risk manager, Chief Risk Officer or CFO, what other factors need to be considered prior to deciding if forming an ACO is a good strategic decision for your organization?

**Overview**

Under Section 3022 of the Patient Protection and Affordable Care Act of 2010 (PPACA), as amended by the Health Care and Education Reconciliation Act of 2010, the Center for Medicare and Medicaid Services (CMS) is required to establish a Medicare Shared Savings Program through the use of ACOs by January 1, 2012. The PPACA and the Proposed Rule describes an ACO as a “formal legal entity that integrates certain clinical and administrative functions of the participating providers in order to achieve improved quality outcomes and cost savings for the Medicare program.” Financial incentives are spelled out in the Act and inure to the ACO if they are successful in achieving specific targets. There is a potential downside for providers; if they are unable to meet the desired targets, they must pay back a portion of the difference. This concept is referred to as a “two sided risk model”.

Creation of an ACO is voluntary and providers (even if they care for Medicare beneficiaries) are not required to form or participate in an ACO. Although initial interest in this model was enthusiastic, it now seems clear that given the requirements in forming an ACO, the cost of establishing such a structure and the obligations and risks which are inherent in the model, that only large networks of physicians and hospitals will be able to form ACOs and benefit from their structure.

**Risk Sharing as a Foundational Concept of ACO’s**

Risk managers and CFO’s understand the concept of risk sharing better than anyone in the health care system. This concept is at the core of the ACO model. While the Shared Saving Program model is described in terms of a “savings” and as a way to control costs, it is essential for the risk manager and CFO to understand what is meant by the term “savings”. The concept of savings in this program is achieved when ACO participants receive less money from Medicare in a year when the receipts are measured against a specific benchmark. In the two sided risk model, the ACO is at risk of owing money back to CMS if the ACO participants receive more money from Medicare in a year than their established benchmark. CMS has proposed to calculate this number by initially setting an “expenditure benchmark” which would be based on the average per capita Medicare payment for an assigned group of Medicare beneficiaries. This benchmark would then be compared against the ACO participants’ Medicare receipts for a contract period of three years. The determinations as to whether there is a savings or a loss would be made annually.

It will be interesting to see of the insurance industry responds to this new risk sharing structure by designing special stop loss type products to protect ACOs from the potential downside risk that may be inherent in ACO operation. Without such products, providers and organizations participating in ACO’s may face significant financial risk.

The ABCs of ACOs
By: Barbara Youngberg
Quality Goals ACOs Hope to Achieve

The purpose of an ACO would not be realized if advances in quality were also not achieved. There are 65 quality measures set forth in the Proposed Rule. They are organized generally around five domains:

- patient - caregiver experience (there are 7 measures in this domain);
- care coordination (there are 16 measures in this domain);
- patient safety (there are 2 measures in this domain);
- preventative health (there are 9 measures in this domain);
- “At risk” population measures (there are 31 measures focused on at risk populations and frail or elderly health).

Many of the “at risk” measures are focused on specific diseases such as diabetes, heart failure, coronary artery disease, hypertension and chronic obstructive pulmonary disease.

As part of this quality mandate, ACOs are also required to establish a quality assurance and process improvement committee that would serve to establish internal processes and performance standards for quality of care processes and outcome improvements. In addition, these committees receive information from the ACOs and must demonstrate that they are able to hold providers accountable for meeting the performance standards.

Those critical of this aspect of ACO structure argue that the quality standards pose major barriers to qualifying as ACOs, create substantial uncertainty, raise serious questions about discriminating against providers serving low-income or vulnerable populations, and may inhibit focused, real-world clinical improvement. Only 11 of the 65 proposed quality measures can be met with claims data; 54 require potentially expensive data collection from medical records or surveys. Other criticism regarding these measures relates to the lack of specificity and face validity surrounding them.

Structuring an ACO

Although the comments regarding the Proposed Rule which were received during the open comment period have not yet been incorporated into the final rule, it would appear from a careful read of the Proposed Rule that the requirements for structuring an ACO will be onerous and expensive. While CMS is not requiring an ACO to be a newly formed entity, very few existing management and governance structures would comply with the requirements for an ACO.

Absent significant changes in the final rule which is due out by the end of the year, the structure of an ACO must include the following features:

- It must be a formal legal entity recognized by State law in the State(s) in which the ACO functions.
- It must have a common governing body (Board of Directors) which has control of specific clinical and administrative functions of the ACO participants.
- At least 75% control of the governing body must be in the hands of the ACO participants.
- It “must demonstrate a mechanism of governance that provides all ACO participants with an appropriate proportionate control over the ACO’s decision making process.”
- The governing body must include a Medicare beneficiary representative.
- It must have an independent administrative structure and financing arrangements for start-up expenses, which describe how the ACO will handle any payments it receives from Medicare and any paybacks to Medicare.
- It must have an executive officer who is appointed to manage the day to day functions of the ACO.
- It must have a compliance program which describes how regulations will be followed for all ACO activities.
- It must have a quality assurance committee which must be established for the ACO and which has jurisdiction over all ACO participants.
- It must have a medical officer who is licensed in the State(s) in which the ACO operates and the medical officer must be physically present in the State(s).

Legal Issues

Obviously the decision to establish an ACO has both strategic and legal implications. In an April 15,
2010 article available on line through the law firm of Pepper Hamilton<br>the author identified both legal and structural issues associated with forming an ACO. Some of the legal issues that will emerge in the creation and operation of an ACO include:

- **Stark Law:**
  Many of the services contemplated by ACOs will include what are characterized as “designated health services” under Stark law, and the contemplated bundled payments will lead to new financial relationships, for which the Stark law exceptions were not contemplated. This is especially true as it relates to splitting incentive payments between a hospital and a physician group and allowing for the structure necessary to meet the requirements of an ACO model.

- **Anti-kickback Laws:**
  It would appear that the key to an ACO’s success which lies in the hospital and physicians negotiating and dividing the savings realized from bundled payment agreements, or providing payments to a home care or rehab provider, would most likely violate past interpretation of acceptable payment arrangements under the Anti-Kickback laws. For an ACO to be successful, it might have to negotiate payments based on quality and volume incentives.

- **Federal Antitrust Laws:**
  Clearly, the FTC and the Department of Justice will need to provide guidance, show flexibility, and allow health care organizations and physicians to be more fully integrated in the interest of promoting both quality and efficiency.

- **Non-Profit Tax Issues:**
  If non-profit hospitals decide to become involved in ACOs, a determination will have to be made as to how the profit sharing potential of an ACO relates to nonprofit tax status. It is possible that specific structures will need to be established so as not to undermine the hospital’s non-profit tax status.

Obviously, there is potential for a number of costly legal issues to emerge if the language of the final rule is not clarified and more clearly aligned with the current judicial interpretations that have defined provider organization relationships and limited the behavior of non-profit entities.

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**Data Sharing Issues and EHR Requirement**

The reporting of quality measures will require that providers have a sophisticated data collection and reporting system. At least 50% of an ACO’s primary care physicians must meet the criteria established for meaningful use of EHR’s, and use EHR technology as defined in the HITECH Act and subsequent Medicare regulations.

This creates an additional economic and regulatory burden on providers and organizations wishing to form an ACO.

**Summary**

The proposed regulations are complex and add substantial regulatory requirements and significant costs, raising barriers to entry that restrict the number and types organizations which can become ACOs. Even if CMS shifts to prospective attribution and substantially improves the financial terms, the extraordinary range of requirements (including quality measures) brings into question the economic viability of ACOs and real impact of shared savings. Clearly, many are hoping that the final rules will address the significant and critical public comments to the proposed rule, which may lead to the resolution of some of these concerns raised. Suffice it to say, at present, the formation of ACOs seems to be a viable option only for large networks of physicians and hospitals, and many of these types of organizations may still question the return on investment.

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