Fox Rothschild LLP
ATTORNEYS AT LAW

Staying Well Within the Law

A newsletter on the current legal issues facing today's health care industry

Fall 2010

ACOs – Health Reform's Latest Approach to Costs and Quality

By William H. Maruca

There is a new acronym floating in the increasingly crowded alphabet soup that is health care, right next to PPACA (Patient Protection and Affordable Care Act). It's ACO, "Accountable Care Organization," adopted as a curve-bending strategy in the recently enacted Patient Protection and Affordable Care Act. Much as HMOs in the 1970s were designed to try to reorient health care toward maintenance of health instead of treatment of disease, the ACO concept is intended to place accountability for quality and costs collectively upon those who are believed to have the most control over them – physicians, hospitals and other community providers.

Under PPACA, ACOs may qualify for Centers for Medicare and Medicaid Services (CMS) incentive payments under health care reform for achieving improvements in quality and reductions in cost based on risk-adjusted shared savings against historical benchmarks. CMS has predicted that regulations clarifying the scope and requirements of the ACO program will be published in the fall of 2010, and a shared savings program is required by the reform law to go live by January 1, 2012.

So far, ACOs are loosely defined, local delivery systems comprising physicians and the hospitals where they work or admit their patients that provide coordinated care and chronic disease management. Sound familiar? If you've been in the business for a while, you may also remember similar claims and goals for integrated delivery systems, gainsharing programs, physician-hospital organizations (PHOs) and medical staff-hospital (MeSH) organizations. Payors' previous approaches included capitation and restricting access to specialists and high-cost services through gatekeeper primary care physicians. What makes the ACO concept different from prior attempts to incentivize management of costs and quality?

One way to distinguish the ACO from its predecessors is to look at what didn't work in the past. For instance, PHOs and integrated delivery systems were designed around fixed payment models such as capitation or fees for episodes of care (remember Highmark's Adesso fiasco?) and shifted economic risks to providers, putting them into the economic role of insurers, but did not give them the tools to work together to achieve either financial or clinical goals. Gainsharing, where hospitals share a portion of their cost savings with the doctors whose decisions generate those savings, has been limited by a thicket of legislative and regulatory restrictions, and only a handful of narrowly focused programs have been approved to date, primarily in cardiology. Capitation and primary care gatekeepers have been largely abandoned by the insurance industry as failing to effectively control costs or improve outcomes.

Elliott S. Fisher, M.D., M.P.H., of Dartmouth, in his paper "Creating Accountable Care Organizations: The Extended Hospital Medical Staff" (*Health Affairs*, Dec. 5, 2006), suggested ACOs avoid the flaw of earlier efforts that incentivized individual providers only for the care within their direct control. Instead, ACOs reward shared accountability for the care of a population of patients spread among a hospital, those physicians providing inpatient work at the hospital and those community physicians whose patients are treated at the hospital (which Fisher calls the "extended medical staff").

Design and Structure

There is no single organizational model for developing an ACO. ACOs may be formed and organized by health systems using employed and contracted physicians, by integrated delivery systems, by physician groups (either primary care or multispecialty) or through joint ventures or contractual relationships among providers. Regardless of the organizational structure, an ACO must be physician-led and physician-driven. Physician leadership is critical because an ACO is primarily a vehicle for clinical integration, not financial or risk integration. Only physicians are able to develop, monitor and adjust clinical care protocols that can more efficiently use resources based on documented effectiveness.

Qualifying ACOs will be assigned a pool of patients whose care the ACO will be responsible for managing in a cost-effective and clinically appropriate manner. The ACO will need to develop internal mechanisms for monitoring and managing costs and quality that cut across traditional reporting lines and result in a higher degree of clinical interdependence than is typical in a less-integrated medical community.

The PPACA states that any of the following groups of providers of services and suppliers that have established a mechanism for shared governance are eligible to participate, in accordance with regulations to be developed by the Secretary of Health and Human Services (HHS):

In This Issue:

- 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; and
- Such other groups of providers of services and suppliers as the Secretary determines appropriate.

ACOs Under Health Reform

Section 3022 of PPACA requires HHS to establish a shared savings program under which qualifying ACOs may be eligible for incentive payments. The criteria in the statute, which will need to be further defined by regulation, include:

- The ACO must be willing to become accountable for the quality, cost and overall care of the Medicare beneficiaries assigned to it.
- Minimum three-year agreement with CMS is required.
- The ACO must establish a formal legal structure to receive and distribute payments for shared savings.
- The ACO must include a sufficient number of primary care professionals to manage the ACO's panel of beneficiaries. (Nobody knows what ratios will be adopted, but California currently requires at least one full-time equivalent primary care provider for each 2,000 enrollees.[1]) At a minimum, each ACO will be assigned at least 5,000 beneficiaries in order to be eligible.
- The ACO must provide HHS with information regarding its participating professionals to support the assignment of Medicare fee-for-service beneficiaries, the implementation of quality and other reporting requirements and the determination of payments for shared savings.
- The ACO must have in place a leadership and management structure that includes clinical and administrative systems.
- The ACO must 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 must be able to demonstrate it meets patient-centeredness criteria, such as the use of patient and caregiver assessments or the use of individualized care plans.

ACOs will be required to measure and report their progress to HHS, including clinical processes and outcomes; patient and caregiver experience of care; and utilization, such as rates of hospital admissions for ambulatory care sensitive conditions. Data reporting requirements may include care transitions across health care settings, including hospital discharge planning and post-hospital discharge follow-up by ACO professionals.

One significant gap in the scheme is how patients will be assigned to ACOs' rosters. PPACA only instructs the Secretary to determine an "appropriate method" to assign Medicare fee-for-service beneficiaries to an ACO based on their utilization of primary care services provided by an ACO professional. It is not clear whether CMS will be able to assign a fee-for-service patient to the ACO that includes the patient's PCP, but to the patient, there may be no economic impact. If a fee-for-service Medicare beneficiary does not want to be in an ACO, perhaps because of perceptions of pressure to ration care, it is not clear if he or she will be permitted to opt out. ACOs may not select their beneficiaries based on risk criteria. If they are caught taking steps to avoid patients at risk in order to reduce the likelihood of increasing costs to the ACO, they may be subject to sanctions including termination from the program.

Most problematically, beneficiaries may not be locked in to receive care only through ACO members, but the ACO remains accountable for the cost and outcomes of their beneficiaries' care. As the rules are developed, look for heavy lobbying to permit ACOs to either limit beneficiaries' access to out-of-network providers or to carve out negative consequences of such utilization from shared savings formulas. Either step may require further Congressional action, and anything that appears to limit patient choice would be hard to sell politically.

Payment Mechanisms

The shared savings program contemplates that ACO member providers will continue to be paid under the original Medicare fee-for-service program under parts A and B in the same manner as they would otherwise, and the ACO would potentially receive additional bonus payments for shared savings if it meets quality performance standards and the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for parts A and B services, adjusted for beneficiary characteristics, beats the applicable benchmark by a percentage to be specified by HHS, which percentage may vary based on the number of Medicare fee-for-service beneficiaries assigned to the ACO. This is the first step toward aligning incentives. The ACO's traditional Medicare payments are not at risk but the ACO may earn bonus payments for achieving cost savings. It looks a lot like the hospital-specific gainsharing programs of the past, but the cost savings are funded by Medicare, not the hospitals.

Several alternative risk-shifting methods are contemplated by PPACA. The Secretary of HHS may offer a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under Medicare parts A and B. The partial capitation model may be limited to ACOs that are highly integrated systems of care and capable of bearing risk, as determined to be appropriate by the Secretary. It is anticipated such a model would offer greater upside opportunities in exchange for bearing more downside risk.

Another alternative method is bundled payments for episodes of care. HHS is authorized to develop payment models that identify certain qualifying medical conditions and bundle payment for the following services: acute care inpatient services; physicians' services delivered in and outside of an acute care hospital setting; outpatient hospital services, including emergency department services and post-acute care services, including home health services and skilled nursing services; inpatient rehabilitation services; and inpatient hospital services furnished by a long-term care hospital, along with any other services the Secretary determines appropriate. An episode of care means the period that includes the three-day window prior to admission, the hospital stay and the 30 days following the patient's discharge. Applicable conditions are to include a mix of chronic and acute conditions, a mix of surgical and medical

[1] http://www.dmhc.ca.gov/library/reports/med_survey/tag/v_aa_01_02_10.pdf

conditions, conditions for which there are opportunities for cost savings and quality improvement, those for which there is significant variation in the number of re-admissions and the amount of expenditures for post-acute care spending, and high volume conditions with high post-acute care costs.

One problem with the bundled payment model is there are no incentives to avoiding an episode of care, i.e., by aggressive preventative care. How the system will reward an ACO for managing a patient who avoids a hospital stay due to effective preventative services remains unanswered.

The Devil in the Details

As noted in many media reports, the phrase "the Secretary shall" appears 976 times in the health reform law. The Secretary of Health and Human Services must put a lot of flesh on the bones of the PPACA before the shared services program becomes a reality. Among the many unanswered questions are:

- How to assign patients to ACOs?
- How to set benchmarks?
- What percentage savings from those benchmarks will qualify for payments?
- What quality measurements and criteria will protect patients from rationing?
- How to avoid cost shifting by non-governmental payors?
- How to adjust payments for patient population risk variations?
- How to account for out-of-network services?
- What to do about mobile patient populations such as "snowbirds" who spend winters in the south and the rest of the year in the north? Which ACO gets credit for their cost savings or dinged for their utilization?
- How much IT and governance infrastructure will be needed to track the statistics required to qualify for shared savings, and what will it cost?
- Will independent or semi-integrated physicians, hospitals and other providers be able to develop the level of trust needed to cooperate to succeed in this new environment?

Some of these questions can and will be answered by the Secretary, but others, particularly those requiring the cooperation of traditional competitors, cannot be imposed by Uncle Sam and must evolve organically.

What Now?

Although many of the details about ACOs remain murky, one clear message is that success will require further integration of clinical decisions, measurement of costs and outcomes, and improved information gathering and reporting capabilities. Larger hospital networks and larger group practices may have an apparent head start due to their size and top-down organizational structure, but independent players who can collaborate, integrate and make informed decisions may ultimately be better positioned to take full advantage of these opportunities. The long-predicted death knell for the mom-and-pop small practice may not have arrived, but by working together to integrate clinically as well as economically, well-organized physician practices may be best ready to lead the development of ACOs.

For more information about this topic, please contact William H. Maruca at 412.394.5575 or wmaruca@foxrothschild.com.

This article first appeared in *The BULLETIN* of the Allegheny County Medical Society and is reprinted here with permission.

Could Your Medicare Billing Privileges Be Revoked?

By Anne E. Jorgensen

In today's ever-changing health care climate, health care providers are looking for some type of stability. In the past, that stability was participation in the Medicare program. Despite the fact the benefits of participating in the Medicare program have become increasingly murky, maintaining participating status remains a hallmark for most health care providers. However, as Medicare moves to maintain costs, more policies and procedures are being instituted that may put a health care provider's billing provider status in jeopardy. Here are some steps that can be taken to ensure you remain in good standing with Medicare as both a billing provider and referring health care provider.

Update Your Enrollment When Necessary

Many health care providers simply "forget" to update their Medicare enrollment. However, a failure to update could cause you to have your Medicare billing provider status revoked. Pursuant to long-standing Medicare rules and regulations, health care providers are required to provide Medicare with certain updates. Within 30 days of occurrence, a provider must notify Medicare of (1) changes in ownership; (2) changes in practice location; and/or (3) final adverse actions. Within 90 days of occurrence, a provider must notify Medicare of (1) change in practice status; (2) change in business structure, legal business name or taxpayer identification number; (3) change in banking arrangements or payment information; and/or (4) change in the correspondence for special payments address.

In April 2010, the Centers for Medicare and Medicaid Services (CMS) issued a transmittal setting forth its updated process for conducting site verifications. CMS is permitted, when it deems necessary, to perform onsite inspections of a health care provider to verify the enrollment information submitted to CMS is accurate and to determine compliance with Medicare enrollment requirements. If CMS visit a practice location no longer being used but not removed from the health care provider's Medicare enrollment, that health care provider's ability to bill Medicare may be revoked.

Similar to the site verifications, CMS may undertake other actions with regard to determining compliance with Medicare enrollment requirements. It is incumbent upon each health care provider to ensure that

his, her or its Medicare enrollment is up-to-date with any changes that may have occurred.

Be Aware of Revalidation Efforts and Respond Accordingly

In September 2009, CMS issued a transmittal setting forth a plan for provider revalidations. The revalidation effort was to focus on the top 50 Part B individual practitioner supplier billers within each state. Each of these health care providers were to be sent a request for revalidation by CMS. Pursuant to the Medicare rules and regulations, the Medicare Administrative Contractor (MAC) is permitted to request revalidation from participating health care providers at any time.

To the extent you receive a request for revalidation, it is imperative you take all appropriate actions to complete the revalidation. Failure to do so could result in a revocation of billing privileges. Already, we have seen revocations stemming from a failure to respond. In some cases the revocations are a result of the health care provider's failure to receive the notice due to misdirected mailings to practice locations or addresses that had not been updated as required. In other cases, it is uncertain as to how a request for revalidation failed to reach the health care provider. Regardless of the reason for the failure to respond, the revocation that results from this failure remains devastating to a practice. As such, health care providers must remain vigilant in responding to any inquiries received from CMS regarding Medicare enrollment.

Enroll in PECOS

CMS had set forth a plan with regard to ordering, referring and providing certain Part B Medicare services requiring those ordering and referring providers to enroll in the Internet-based Provider Enrollment, Chain and Ownership System (PECOS). As proposed, during phase 1, October 5, 2009, to January 2, 2011, if a billed item or service was not ordered or referred by a provider with an active PECOS enrollment, the claim would be processed and the provider would receive a warning message on the Remittance Notice indicating the provider must enroll in PECOS. During phase 2, which was to begin on January 3, 2011, if a billed item or service was ordered or referred by a provider without an active PECOS enrollment, the claim would be denied.

However, in the interim final rule set forth with regard to the new Patient Protection and Affordable Care Act (PPACA), those deadlines were accelerated. As of July 6, 2010, ordering and referring health care providers must be enrolled in PECOS as of the date of the order or referral to enable the MAC to verify the provider's enrollment (or Medicare opt-out status, if applicable). If the MAC is unable to verify the ordering or referring health care provider's enrollment using PECOS, the MAC may deny claims for such services.

Recognizing the inevitable chaos that would ensue with this changed deadline, CMS set forth a June 30 news release indicating "CMS will, for the time being, not implement changes that will automatically reject claims based on orders, certifications and referrals made by providers that have not yet had their applications approved by July 6." It is anticipated the original deadline of January 2, 2011, will be reinstated when the final rule is issued this fall.

To remain in compliance with the new rules and to remain on the good side of those who provide Part B services for your patients, you need to take the appropriate steps to enroll in PECOS prior to the implementation of the deadline, whenever that may be. In addition, once you enroll in PECOS, you will be able to update your Medicare enrollment with regard to many of the required enrollment updates mentioned herein.

What Is Revocation?

Some of you may be thinking, how much could revocation really affect me? If it is an innocent overlook, wouldn't I be able to fix it relatively easily? The short answers to those questions are (1) a lot and (2) no. If your Medicare billing privileges are revoked, in most cases the revocation is effective 30 days after CMS or the MAC mails notice of its determination. Once revoked, you are barred from billing or participating in the Medicare program until the end of the re-enrollment bar. The re-enrollment bar is established by the MAC in accordance with the following:

> "1 year – License revocation/suspension that a deactivated provider (i.e., is enrolled but is not actively billing) failed to timely report to CMS; provider failed to respond to revalidation request.
>
> 2 years – The provider is no longer operational.
>
> 3 years – Medical license revocation/suspension and the practitioner continued to bill Medicare after the license revocation/suspension/felony conviction and the practitioner continue to bill Medicare after the date of the conviction; falsification of information." (Medicare Program Integrity Manual, Chapter 10, Section 13.2)

As such, a failure to respond to a revalidation request will revoke billing privileges for at least one year, and a failure to update information such as a site location could result in a two-year revocation. Therefore, a simple mistake could have lasting implications on your practice, as your patients will be forced to seek other care during your revocation period and your income will likely decrease with your decreased patient volume. Additionally, once your billing privileges are reinstated, your Medicare patients who sought care elsewhere may not return.

With the penalties associated with revocation being so high, it is in each Medicare health care provider's best interest to be aware of the ever-changing Medicare landscape and remain in compliance with the rules and regulations related thereto. Think of your Medicare enrollment and compliance the same way you think of the medical care you provide: prevention is the best treatment and solution!

For more information about this topic, please contact Anne E. Jorgensen at 610.458.4950 or ajorgensen@foxrothschild.com.

This article first appeared in *BC Advantage Magazine* and is reprinted here with permission.

Charity Care Matters for Hospital EHR Incentive Payments

By Elizabeth G. Litten

The recently published final "meaningful use" regulations make it clear hospitals must be careful in how they report charity care on their Medicare cost reports if they want to maximize their incentive payments for using electronic health records (EHR). The amount a hospital receives in EHR incentive payments is calculated based on the hospital's Medicare and Medicaid patient volume, calculated as a fraction of the hospital's total patient volume. The rule proposal failed to define key terms that are part of the calculation of the fractional share of the hospital's Medicare and Medicaid patient volume, including the term "charity care." The proposed final rule looks to the charity care amount reported in the hospital's Medicare cost report, despite the fact this reported number likely did not have a significant impact on the hospital's Medicare reimbursement in the past.

As the Centers for Medicare and Medicaid Services (CMS) explains in the preamble to the rule, "We believe that the charity care charges reported on line 20 of the pending final OMB approved Worksheet S-10 [Form CMS-2552-10, effective for cost reporting periods beginning on or after May 1, 2010] represent the most accurate measure of charity care charges as part of the hospital's overall reporting of uncompensated and indigent care for Medicare purposes... if a hospital has not properly reported any charity care charges on line 20, we may question the accuracy of the charges used for computing the final Medicare share of the [EHR] incentive payments."

CMS goes on to explain charity care data can be obtained by the Medicare contractor, and the data "would be used to determine if the hospital's charity care criteria are appropriate, if a hospital should have reported charity care charges, and if the reported charges are proper. If we determine, as based on a determination of the MAC, that the hospital did not properly report charity care charges on line 20 of the pending final OMB approved Worksheet S-10, then we propose to deem the [charity care] portion of the denominator ... to be 1." Instructions to draft Form CMS-2552-10 for Worksheet S-10 define "charity care" as "[h]ealth care services for which a hospital demonstrates that the patient is unable to pay ... [and] results from a hospital's policy to provide all or a portion of services free of charge to patients who meet certain financial criteria." Conversely, "non-Medicare bad debt" is defined as "[h]ealth care services for which a hospital determines the non-Medicare patient has the financial capacity to pay, but the non-Medicare patient is unwilling to settle the claim."

CMS makes clear that just as Medicare contractors currently determine whether a hospital's indigency policies (for example, how a provider determines a non-Medicaid patient is indigent or medically indigent and the patient's financial condition is not likely to improve following an asset/income test of patient resources) are appropriate for determining allowable Medicare bad debt, the Medicare contractor can similarly determine whether the hospital's policies are sufficient for determination of charity care information used in the EHR incentive payment calculation.

In short, a hospital seeking EHR incentive payments must closely examine not just the accuracy of reported charity care and non-Medicare bad debt data included on its Medicare cost report, but also must ensure it is actually undertaking a review of patients' ability to pay for services. Failure to document the proportion of uncompensated care that qualifies as "charity care" may result in a decrease in EHR incentive dollars.

For more information about this topic, please contact Elizabeth G. Litten at 609.895.3320 or elitten@foxrothschild.com.

Coming Clean: CMS Releases Self-Disclosure Protocol for Stark Violations

By William H. Maruca

The Stark self-referral law can be unforgiving. Unintentional minor technical violations can result in severe penalties and staggering refund liabilities. Until recently, there was no way a physician or provider could come forward and voluntarily disclose such violations to the enforcement agencies, and in an Open Letter dated March 24, 2009, the Office of Inspector General announced it will no longer accept disclosure of a matter that involves only liability under the physician self-referral law in the absence of a colorable anti-kickback statute violation under its 1998 Provider Self-Disclosure Protocol. This policy left providers with limited options when a Stark violation was discovered. The Patient Protection and Affordable Care Act (PPACA) changed all that, up to a point.

On September 23, 2010, six months after the enactment of health reform under the PPACA, the Centers for Medicare and Medicaid Services (CMS) published a Voluntary Self-Referral Disclosure Protocol, which can be found at https://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf. This protocol allows any physician or provider to disclose actual or potential Stark violations.

More good news under the PPACA: the new law grants the Secretary of Health and Human Services discretion to reduce the amounts due for Stark violations and directs the Secretary to consider as mitigating factors the nature and extent of the improper or illegal practice; the timeliness of such disclosure; the cooperation in providing additional information related to the disclosure; and such other factors as the Secretary considers appropriate. The CMS

protocol adds two more factors: the litigation risk associated with the matter disclosed and the financial position of the disclosing party.

Currently, a provider must refund all Medicare payments for designated health services referred by a physician where a non-exempt financial relationship with the physician (or a family member) exists. The new protocol does not guarantee leniency, either with regard to the refund obligations or with regard to any Stark or False Claims Act penalties.

All disclosures must be made electronically and include the following information:

- The name, address, national provider identification numbers (NPIs), CMS Certification Number(s) (CCN) and tax identification number(s) of the disclosing party.
- A description of the nature of the matter being disclosed, including the type of financial relationship(s), parties involved, specific time periods the disclosing party may have been out of compliance; type of designated health service claims at issue; type of transaction or other conduct giving rise to the matter; and the names of entities and individuals believed to be implicated and an explanation of their roles in the matter.
- A statement from the disclosing party regarding why it believes a violation of the physician self-referral law may have occurred, along with a description of the potential causes of the incident or practice (e.g., intentional conduct, lack of internal controls, circumvention of corporate procedures or government regulations).
- The circumstances under which the disclosed matter was discovered and the measures taken upon discovery to address the issue and prevent future abuses.
- A statement identifying whether the disclosing party has a history of similar conduct or has any prior criminal, civil and regulatory enforcement actions (including payment suspensions) against it.
- A description of the existence and adequacy of any pre-existing compliance program and the measures or actions taken by the disclosing party to restructure the arrangement or non-compliant relationship.
- A description of appropriate notices, if applicable, provided to other government agencies, (e.g., Securities and Exchange Commission and Internal Revenue Service) in connection with the disclosed matter.
- An indication of whether the disclosing party has knowledge the matter is under current inquiry by a government agency or contractor.
- A full financial analysis must also be completed for the applicable "look-back period."

CMS makes it clear this protocol is not to be used to elicit advisory opinions about Stark compliance, and such requests should go through the existing Advisory Opinion process, which has been less than robust to date when compared to OIG's Advisory Opinion process.

Don't try this without help. Because of the volume of information required, providers and physicians who become aware of Stark violations should consult with experienced health law counsel before approaching CMS under the self-disclosure protocol.

For more information about this topic, please contact William H. Maruca at 412.394.5575 or wmaruca@foxrothschild.com.

About the Health Law Practice

Fox Rothschild's Health Law Group comprises more than 40 attorneys who counsel clients locally, regionally and nationally. Our multioffice, multidisciplinary approach allows us to offer practical, cost-effective solutions to issues faced by longstanding stakeholders, as well as a variety of industry newcomers.

For more information about any of the articles in **Staying Well Within the Law**, please contact any member of the Fox Rothschild Health Law Practice. Visit us on the web at **www.foxrothschild.com**.

Practice Co-Chair
David S. Sokolow
215.299.2712 or 609.895.3308
dsokolow@foxrothschild.com

Practice Co-Chair
Todd A. Rodriguez
610.458.4978
trodriguez@foxrothschild.com

Newsletter Editor
William H. Maruca
412.394.5575
wmaruca@foxrothschild.com