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CORRIDORS

News for North Carolina Hospitals
from the Health Law Attorneys of Poyner Spruill LLP

New Requirements for Tax-Exempt Hospitals

by Pearl Doherty

As part of the Patient Protection and Affordable Care Act, Congress enacted earlier this year a new tax provision, Section 501(r) of the Internal Revenue Code. This provision imposes four new, additional requirements upon hospitals that are recognized as tax-exempt under Section 501(c)(3).

These new requirements specifically apply to any organization that operates a facility required by a state to be licensed, registered, or similarly recognized as a hospital, as well as any other organization that the Secretary of the Treasury determines has the provision of hospital care as its principal function or purpose constituting the basis for its tax exemption under Section 501(c)(3). If a hospital organization operates more than one facility, it must meet the requirements of this provision separately with respect to each facility.

- **Community Needs Health Assessment.** The first requirement is that a hospital must conduct a community health needs assessment every three years and adopt an implementation strategy to meet the community health identified from that assessment. A hospital must include in its annual information return, Form 990, a description of how it is addressing these needs, as well as a description of any needs that are not being addressed and the reasons why not. An excise tax may be imposed on hospitals that fail to meet these requirements. This new requirement is effective for taxable years beginning after March 23, 2012.
- **Financial Assistance and Emergency Care.** The second requirement is that a hospital establish both a financial assistance policy and a policy relating to emergency medical care. A financial assistance policy must include eligibility criteria for financial assistance and whether that assistance includes free or discounted care; the basis for calculating amounts charged to patients; the method for applying for financial assistance; for organizations that do not have separate billing and collections policies, the actions the organization may take in the event of nonpayment; and measures to widely publicize the financial assistance policy in the community. A hospital must also have a written policy requiring it to provide care for emergency medical conditions without discrimination. This policy is required to prevent discrimination in providing emergency treatment against those eligible for either financial assistance under the hospital's policy or government assistance.
- **Limitation on Charges.** Third, a hospital must limit the amount it charges for emergency or other medically necessary care that is provided to individuals eligible for financial assistance to not more than the amounts generally billed to individuals who have insurance. The legislative history indicates that the amount billed to those who qualify for financial assistance should be based on either the best, or an average of the three best, negotiated commercial rates or Medicare rates.

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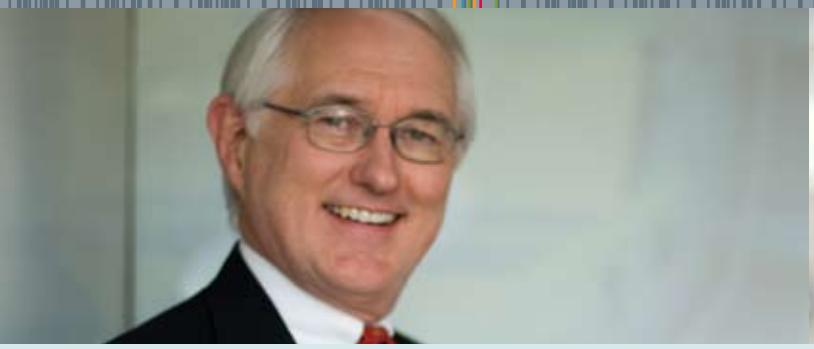

Accountable Care Organizations: The Opportunity of a Lifetime or a Pitfall for the Unwary?

by Steve Shaber, Kim Licata, and Justin Puleo

Introduction

More than six months have passed since the Patient Protection and Affordable Care Act (PPACA) became law in March, but many questions still linger. At the same time, many opportunities for leadership and innovation remain. One opportunity-filled area of special interest to hospitals and physicians is that of Accountable Care Organizations (ACOs). Section 3022 of the PPACA states that by January 1, 2012, the Secretary of Health and Human Services (HHS) shall establish a shared savings program under the Centers for Medicare and Medicaid Services (CMS) that promotes accountability for Medicare patient populations. Section 3022 lays out what HHS considers the rough framework for ACOs as a means by which cost savings can be achieved.

By definition, ACOs are entities that will become accountable for the overall cost and quality of health services delivered to patients through increased integration and coordination of care. Provided that quality benchmarks are met, greater accountability for cost will be encouraged by shared savings incentive payments. In terms of specifically required elements, Section 3022 states that ACOs shall:

- Be accountable for the quality and cost of care;
- Participate in the program for at least three years;
- Have a formal legal structure;
- Have at least 5,000 Medicare beneficiaries;
- Provide the secretary with information on ACO professionals;
- Maintain clinical and administrative management structure;
- Promote evidence-based medicine and coordinated care; and
- Meet patient-centeredness criteria specified by the secretary.

Any type of provider can participate in ACOs and participate in shared savings under PPACA. Both the North Carolina Hospital Association and the North Carolina Medical Society have taken a positive view of ACOs and have encouraged members to consider the opportunity. Despite several unanswered questions, an early consensus is forming that ACOs show considerable promise for those willing and able to invest the time and resources necessary to achieve innovative integration.

AHA Research Synthesis Report

Among the many groups taking notice of ACOs is the American Hospital Association. In June 2010, it published Accountable Care Organizations: An AHA Research Synthesis Report (the AHA Report), available at http://www.hret.org/accountable/index.shtml. The AHA Report outlines six key considerations for hospitals in the development and implementation of ACOs:

- What are the key competencies required for ACOs?
- How will ACOs address physician barriers to integration?
- What are legal and regulatory barriers to effective ACO implementation?
- How can ACOs maintain patient satisfaction and engagement?
- How will quality benchmarks be established?
- How will savings be shared among ACOs?

The AHA Report's conclusion is that ACOs require certain core competencies and resources in which providers must be willing to invest. In terms of necessary core competencies, the AHA points to IT infrastructure, patient education resources, team-building capabilities (so as to include the most effective care providers), and quality reporting and monitoring systems. Again, despite several unanswered questions, the AHA Report states that ACOs are a potential opportunity for improving both quality and cost control through increased care coordination.

Further Considerations for Hospitals

In addition to the legal considerations cited by the AHA above – which include Stark, Anti-Kickback, Anti-Trust, Civil Monetary Penalties and other prohibitions against gainsharing, and Federal False Claims Act concerns – participating in an ACO presents other concerns for hospitals. While the legal considerations

will hopefully be addressed in time through explicit federal exceptions, safe harbors, safety zones, and waivers, practical considerations will still exist for many small hospitals.

Models of integrated care often cited by ACO advocates include the Mayo Clinic, Kaiser Permanente, and the Cleveland Clinic. While these organizations are certainly success stories, they are hardly typical hospitals or health care organizations. For ACOs to be successful in achieving true health care change, small hospitals and providers must also be participants, and yet they are fundamentally different than a massive, resource-laden health system. ACOs will not change the face of health care if they are dependent on the nationwide re-creation of many Mayo Clinics or other such highly integrated health care systems. Such a process would necessitate the absorption of small hospitals into large networks, an unlikely, often infeasible and unwanted proposition. Thankfully, PPACA does not require this consolidation and leaves many of the specifics of ACO creation up to providers. In terms of size, all that is required is that the ACO provide services to 5,000 Medicare beneficiaries. Economies of scale would mean, however, that the larger the ACO, the more potential shared savings there will be.

Conclusion

ACOs present hospitals and other providers with a unique opportunity to shape their future. While the government has established some requirements for ACOs, these requirements are fairly flexible and permit providers to use different models and methods to achieve similar desired results of cost savings and quality care. While many believe that the recent reforms did not go far enough to address spiraling health care costs, ACOs provide an opportunity to control and curb costs over a given population while ensuring quality. ACOs may provide the right incentives and a window of opportunity for creative health providers to develop sustainable solutions to the cost problem without sacrificing patient care. ACOs do not promise a one-size-fits-all answer for every locality. This is why providers must lobby CMS for flexibility and explicit legal exceptions before it releases its ACO regulations sometime later this year. Additional information can be found by signing up for updates on the CMS website under Special Open Door Forums. With ACOs, like so many things, the future belongs to the brave.

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New Requirements...
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- **Collection Actions Restricted.** Fourth, a hospital must forego extraordinary collection actions against individuals before it has made reasonable efforts to determine whether the individual is eligible for assistance under its financial assistance policy. Extraordinary collections may include lawsuits, liens on residences, and arrests. Reasonable efforts may include providing notification of the hospital's financial assistance policy upon admission and in communications regarding the patient's bill.

Except for the community health needs assessment requirements, the new provisions are effective for taxable years beginning after March 23, 2010.

The Internal Revenue Service requested, and is now considering, comments submitted concerning these new provisions by the American Hospital Association and others. Comments were requested on particular areas of concern, including what should be the appropriate requirements for a community health needs assessment, what should constitute reasonable efforts to determine eligibility for assistance, and what should be the consequences to a hospital organization where some, but not all, of the facilities meet the standards of Section 501(r).

We recommend that hospitals begin reviewing their policies for compliance with the requirements of Section 501(r). Financial assistance policies should be reviewed for compliance with the new law, or where there are none, such policies should be put in place. Similarly, emergency treatment policies, as well as billing and collection policies, need to be reviewed and revised if needed. In addition, community needs assessments should be reviewed, though there is more time to undertake this review since this part of the law is not effective until 2012. Hospitals should be sure to report, as appropriate, compliance with these measures on Schedule H of their annual information return filed with the IRS.

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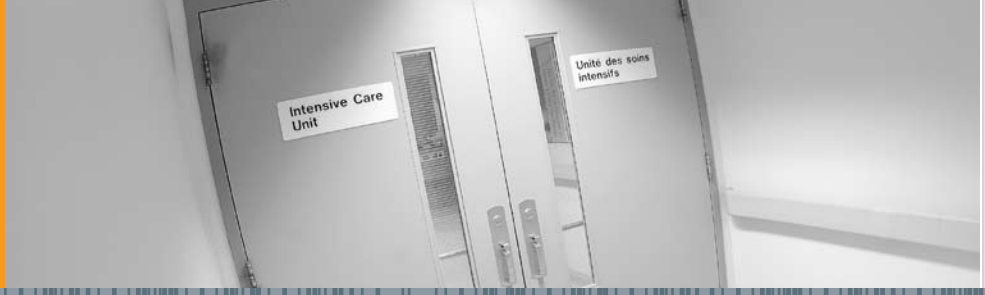

CON Section, May I?

by Pam Scott

Are you thinking of replacing an aging MRI unit, or upgrading a linear accelerator with new imaging and treatment planning programs? Planning to move bed capacity to or from an affiliated facility? Considering a joint venture with a physician group? Depending on the particulars, some of these projects could raise issues under North Carolina's certificate of need (CON) Law. Either way, a provider will almost always want to ask, "CON Section, may I?"

Even for projects that do not require CON review, the prudent action plan begins with confirming a project's exempt or no-review status from the get-go by first defining what you want to accomplish, with input from your CON attorney, and then checking in with the CON Section. Indeed, prior written notice to the CON Section is required for several types of projects that are specifically exempt from CON review in order to demonstrate that a proposed project qualifies for the exemption.

Restrictive lending markets, decreased reimbursement, and other factors are causing some providers to change course on projects for which they have CONs in hand but have not yet completed – which they can do, provided the project continues to materially comply with the approved application and the conditions of the issued CON. Just as with new undertakings, a provider planning changes to an ongoing CON project will usually want to make sure the CON Section agrees that the revised project will continue to be consistent with the application and the CON.

An early consult with legal counsel regarding a project's exempt or no-review status can help you anticipate potential questions and legal challenges from the CON Section or a competitor and shape the details of your project accordingly. Familiarity with the agency's current hot-button issues and recent developments from appellate court opinions applying the CON Law are often key to developing a successful proposal. For larger undertakings or projects expected to be opposed by a competitor, you may also want to informally explore the details of the proposed project with the CON Section before seeking an official written determination. Clearly presenting a no-review, exemption, or material compliance question to the CON Section in a way that addresses possible legal as well as factual questions can make all the difference in terms of getting a timely, affirmative decision from the agency and undercutting or sidestepping potential legal challenges to the project. Better to deal with a question or potential legal obstacle before your project gets rolling and major expenses are incurred than to be pulled up short in the midst of development, which can result in costly delays and lost opportunities.

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From the Marketing Department

Several Poyner Spruill Health Law attorneys were recently named to the 2011 edition of *Best Lawyers In America*®, the oldest and most respected peer-review publication in the legal profession. This designation is based on an exhaustive annual peer-review survey involving more than 3.1 million detailed evaluations of lawyers by other lawyers. Members of the PS health law team named in the 2011 Edition of *Best Lawyers in America*® include the following.

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Important Changes to HIPAA Proposed by HHS

by Elizabeth Johnson

The following summarizes major changes to and new provisions of the HIPAA Privacy, Security, and Enforcement Rules proposed by the Department of Health and Human Services (HHS) in its notice of proposed rulemaking published July 14, 2010 (75 Fed. Reg. 40867). Many of these changes are proposed to implement the HITECH Act, but several of the changes go beyond the provisions of the statute. Other topics covered in this rulemaking were not raised by the HITECH Act and are instead proposed to address issues HHS has identified based on its experience interpreting and administering the rules. Some subjects covered by the HITECH Act, such as breach notification and accounting for disclosures from electronic health records, were not covered in this rulemaking and so are not discussed in this summary. The public comment period on this proposed rulemaking ended September 13, 2010. *Unless otherwise noted below, the compliance deadline for these proposed requirements will be 180 days from the date of publication of the final rule.*

While there are many reasons for the regulated community to be concerned about these and other recent changes to HIPAA regulations, some of the more compelling reasons include:

- Covered entities must notify affected individuals, such as patients and customers, in the event of a security breach affecting unsecured protected health information; notification also must be made to the primary regulator (HHS), which has authority to enforce against any legal violation that may have occurred.
- Recent revisions to the Enforcement Rule changed the maximum annual penalty per identical violation from $25,000 to $1.5 million, a 60-fold increase.
- The interim final Breach Notice Rule has been effective for almost one year, during which time more than 140 covered entities have reported to HHS breaches of unsecured PHI affecting more than 4.8 million individuals (and those figures account only for individual breaches that affected more than 500 people each, meaning their occurrence is immediately noted on HHS's website).
- In addition to making HHS compliance audits mandatory, the HITECH Act authorized state attorneys general to enforce HIPAA; the first such action settled with an agreement by the covered entity to implement a corrective action plan and pay $250,000 in damages.
- Two recent enforcement actions by HHS involving the insecure disposal of health information netted a combined $3.25 million for HHS; the agency has reportedly said it will apply those moneys to fund additional enforcement actions and audits.
- Business associates now must comply fully with the Security Rule, which imposes substantial administrative, physical, technical, and organizational security requirements.
- If the proposed changes are finalized as written, business associates will be directly liable for HIPAA violations.
- If the proposed changes are finalized as written, covered entities will no longer be able to escape liability for business associates simply by virtue of having put appropriate contracts in place and not having known of any pattern or practice of violations by the business associate.

The attorneys of Poyner Spruill's Privacy and Information Security practice regularly assist clients with HIPAA implementation and counsel organizations of all shapes and sizes on their HIPAA obligations, compliance posture, and risk. We provide this summary to assist your organization in commenting on these rules or implementing anticipated changes. A more in-depth summary of proposed changes to HIPAA privacy, security, and enforcement rules can be found on our website at www.poynerspruill.com/publications/Pages/ChangestoHIPAAHHS.aspx.

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New Employer Obligations to Nursing Mothers Under the Fair Labor Standards Act

by Danielle Barbour

The Department of Labor recently issued a fact sheet addressing the new break time requirement for nursing mothers mandated by the Patient Protection and Affordable Care Act (PPACA). The PPACA was signed into law on March 23, 2010, and amended Section 7 of the Fair Labor Standards Act (FLSA). The new FLSA amendments require all employers covered by FLSA to provide "reasonable break time for an employee to express breast milk for her nursing child for one year after the child's birth each time such employee has the need to express the milk." Only nonexempt employees are entitled to breaks to express milk under the amended regulations. Moreover, employers are not required to compensate nursing mothers for breaks taken for the purpose of expressing milk unless they already provide compensated breaks. In that case, employees who use their break time to express milk must be compensated in the same way that other employees are compensated for break time.

In order to be in compliance with the regulation, employers must provide "a place, other than a bathroom, that is shielded from view and free from intrusion from coworkers and the public, which may be used by an employee to express breast milk." If the space provided is not solely for the use of nursing employees, it must be made available when needed. Temporary spaces created for nursing mothers to express milk are sufficient so long as the space meets the statutory requirement that it be "shielded from view and free from intrusion of coworkers and the public."

Employers with fewer than 50 employees may be exempt from the new break time requirement if compliance with the provision would pose an "undue hardship." The existence of undue hardship will be determined by looking at "the difficulty or expense of compliance for a specific employer in comparison to the size, financial resources, nature, and structure of the employer's business."

This new provision was effective on March 23, 2010, when the PPACA was signed into law. The Department of Labor has not yet determined the penalties for noncompliance.

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