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INSIDE:

Message from the Chair

by Lester J. Perling, Esq., Broad and Cassel, Fort Lauderdale, Florida

For years, many have advocated for critical healthcare reforms in Florida. Over the past decade, Florida has witnessed healthcare-related budget battles, funding cuts, and fraud, and at the same time, the number of uninsured Floridians continues to surge. The passing of national healthcare legislation under the Obama administration may bring immediate benefits to Florida in the form of billions of dollars in federal funding, and changes in health insurance coverage, healthcare delivery, and healthcare technology. Some argue that Florida's economic future relies in part on these promised benefits. Benefits, affecting Florida residents, providers, and insurers, include:

- Closing the Medicare Part D "doughnut hole" by the year 2020;
- Funding existing Community Health Centers and the construction of new centers;
- Insurance coverage for young adults seeking to remain on their parents policy until age 26;
- Affordable insurance coverage for uninsured Florida residents with pre-existing medical conditions;
- Insurance plan protections such as bans on dropping sick people, elimination of lifetime caps, streamlined appeal

See "Health Law" page 19

The Stark Law Self-disclosure Protocol: Apply With Care

by Chris M. Morrison, Esquire, Orlando, Florida*

On September 23, 2010, the Centers for Medicare and Medicaid Services ("CMS") posted the Voluntary Self-referral Disclosure Protocol ("Protocol") on its website. The Protocol allows providers and suppliers ("disclosing parties") to self-disclose actual or potential violations of the federal physician self-referral statute (42 U.S.C. §1395nn, commonly known as the Stark Law) and possibly settle their financial liability for such violations for less than the full amount due. The Secretary of HHS (the "Secretary") was required to establish a self-disclosure protocol under the Patient Protection and Affordable Care Act ("PPACA"). PPACA also authorized the Secretary of HHS to reduce the amount due and owing for Stark Law violations.

This article discusses generally some of the main provisions of the Protocol, as well as some of the risks and drawbacks that a disclosing party should consider before deciding to use the Protocol. This article is not exhaustive of all aspects of the Protocol.

General Disclosure Requirements

A disclosure under the Protocol must contain three things: a description of the actual or potential violation or violations; a financial analysis setting forth the total amounts believed

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to be due and owing; and a certification by the disclosing party that the information provided is truthful and based on a good faith effort to resolve the matter at hand. The disclosure must be provided electronically and in hard copy to the addresses specified in the Protocol.

The description must contain detailed factual disclosures and legal analysis regarding the actual or potential violation. A summary of the required content is as follows:

- Identifying information, including organizational relationships if the disclosing party is owned, controlled, or otherwise part of a system or network, and affected corporate divisions, departments or branches.
- A description of the matter being disclosed, including the financial relationships and parties involved; the time periods of the violation and when the conduct was cured, if at all; the type of transaction or other conduct involved; and the names of the entities and individuals believed to be implicated and an explanation of their roles.
- A statement regarding why the disclosing party believes a violation of the Stark Law may have occurred, including a complete legal analysis of the Stark Law's application to the conduct, any Stark Law exceptions that apply and/or that the disclosing party attempted to use, and which elements of the applicable exception(s) were and were not met. It should also describe the potential causes of the violation, such as intentional conduct, lack of internal controls, or circumvention of corporate procedures or government regulations.
- The circumstances of discovering the violation, and the measures taken both to address it and to prevent future abuses.
- A statement of whether the disclosing party has a history of similar conduct or has any prior criminal, civil, and regulatory enforcement actions against it.
- A description of the existence and adequacy of a pre-existing compliance program and efforts to prevent recurrence of the incident, including measures to restructure the non-compliant arrangement or relationship.
- A description of notices provided to other government agencies in connection with the disclosed matter.
- An indication of whether the disclosing party has knowledge that the matter is under current investigation or inquiry by a government agency or contractor.

The disclosing party is expected to conduct a financial analysis and furnish its findings to CMS as part of its initial submission. The analysis should provide a total amount, itemized by year, that is actually or potentially due and owing for the period during which the disclosing party may have been out of compliance with the Stark Law. The disclosing party must also describe the methodology it used to determine these amounts.

Finally, the disclosing party must provide a signed certification stating that, to the best of the individual's knowledge, the information provided contains truthful information and is based on a good faith effort to bring the matter to CMS' attention for the purpose of resolving any potential liabilities under the Stark Law. This certification may be provided by the disclosing party's CEO, CFO or other authorized representative.

Coordination with Other Agencies

CMS will coordinate with the Office of the Inspector General ("OIG") and the Department of Justice ("DOJ"), and may also refer the disclosed matter to law enforcement. CMS may use the disclosure to prepare recommendations to OIG and DOJ for resolution of False Claims Act, civil monetary penalty, or other liability. Thus, a disclosure under the Protocol may result in contact from other government agencies.

Investigation Phase

After CMS receives the disclosure

continued, next page

Editor's Note

by Thomas P. Clark, Esq., Fort Myers, Florida*

Welcome to the latest edition of the Florida Bar Health Law Section e-newsletter. This edition contains six articles covering the following topics: (a)The Stark Law Self-disclosure Protocol: Apply with Care; (b) ACO's: A Work in Progress; (c) Medical Staff Credentialing: Responsibility and Liability of Hospital Boards; (d) Law Firm Compliance with HIPAA's Ugly Stepsister: The HITECH Act; (e) Medicare Revocation of Provider Status - The Newest Threat to Medicare Providers; and (f) Aggravated Identity Theft Statute as a New Prosecutorial Tool Against Health Care Fraud.

On behalf of the Health Law Section, I would like to thank the staff at the Florida Bar for their assistance with this edition. I also would like to thank the authors who submitted articles for publication. Without their help and support it would not be possible to continue the newsletter.

If you are interested in submitting articles for publication, please submit them to me at thomas.clark@henlaw.com. I look forward to working with you.

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it will begin verifying the information provided. During this process, CMS expects to receive documents and information from the disclosing party without having to use "compulsory methods," and to have access to all financial statements and other supporting documents without the assertion of privileges. Any matters discovered during this process which are not part of disclosure will be treated as being outside the Protocol.

CMS states that in the "normal course of verification" it will not ask disclosing parties to produce written communications subject to attorney-client privilege. CMS might more aggressively seek documentation covered by attorney work product, but is "prepared to discuss" ways to get the underlying information without a waiver of privilege. Assertion of privilege should be made advisedly, as the disclosing party's cooperation with CMS during the investigation process is a factor considered in reducing the disclosing party's financial liability, and failing to fully cooperate may result in removal from the Protocol.

Reduction of Amounts Owed

The Protocol lists five factors which CMS may consider in reducing amounts otherwise owed. These include the following:

- Nature and extent of the improper or illegal practice
- Timeliness of the self-disclosure
- Cooperation in providing additional information related to the disclosure
- Litigation risk associated with the matter disclosed
- Financial position of the disclosing party

The Protocol does not further discuss what types of Stark Law violations are more likely to be settled for less than the full amount due. CMS will make an individual determination based on the facts and circumstances surrounding each violation. However, since CMS is authorized, but not required, to reduce amounts due, there is no guarantee CMS will do so. Also, CMS will not accept refunds of overpayments until its investigation is complete, and the disclosing party may not make such payments to the federal health care programs or their contractors without CMS' prior consent.

Timing Issues

PPACA established a 60-day deadline for reporting and returning overpayments, which applies to overpayments occasioned by a violation of the Stark Law.[1] This may mean that a disclosing party, if it wishes to use the Protocol and remain in compliance with this deadline, must make the disclosure before the expiration of these 60 days. This 60-day period will be suspended by the Secretary during the disclosure process until a settlement agreement is reached, or the disclosing party withdraws or is removed from the Protocol. However, the Secretary's authority to suspend this deadline is not apparent in the statutory provision establishing the deadline, nor is it clear what effect, if any, this will have on other relevant government agencies.

Risks and Limitations

The Protocol provides no guarantee that CMS will allow a disclosing party to pay less than the full amount due and owing for the disclosed Stark Law violation. Even if CMS settles for a reduced amount, there is no indication that such settlement binds any other government agency. Since other governmental agencies will likely become aware of the disclosure, disclosing providers will need to take this into consideration. It is also unclear whether the Protocol only covers settlement of the overpayment resulting from the Stark Law violation, or includes settlement of potential civil monetary penalties as well. Until this is clarified, the Protocol may have narrow utility in limiting a disclosing party's financial liability for an actual or potential Stark Law violation.

Another issue is the requirement to provide detailed facts and a "complete legal analysis" of the potential violation. This may provide CMS and other agencies with a roadmap to build a case against the disclosing party for monetary liability, penalties and other sanctions. It may also compromise the disclosing party's ability to raise factual or legal defenses in those actions. Further, disclosing parties currently subject to a corporate integrity agreement ("CIA") or certification of compliance agreement ("CCA") may have additional reporting requirements. The matters disclosed under the Protocol may also constitute a breach of the CIA or CCA, which can result in penalties to the disclosing party. These factors should all be considered when deciding whether to disclose, and in preparing the disclosure statement.

There are other conditions to using the Protocol that disclosing parties should consider. One condition is agreeing that there are no appeal rights for claims resolved through a settlement agreement. Also, disclosing parties must agree that if they are denied acceptance into the Protocol, withdraw from the Protocol or are removed from the Protocol, the reopening rules for Medicare payments apply from the initial date of disclosure to CMS. Ordinarily, a Medicare contractor may reopen and revise payment determinations or redeterminations either one year or four years (if there is good cause) from the date of its initial determination or redetermination. Accordingly, if the disclosing party is unsuccessful in using the Protocol for the reasons described above, the clock is reset for Medicare contractors to reopen their determinations and potentially assess an overpayment.

Conclusion

For the first time, CMS has provided suppliers and providers with a specific process for disclosing and settling potential liability under the Stark Law. However, the Protocol does not guarantee that a disclosing party will be able to settle its potential Stark Law liability with CMS, and settlement does not necessarily protect against liability and sanctions from other sources. There are also risks and tradeoffs within the Protocol that may result in greater uncertainty and exposure to the disclosing party. Accordingly, the decision to use the Protocol must be carefully considered on a case by case basis.

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Endnote:

[1] Overpayments must be reported and returned by the later of 60 days after the date on which the overpayment was identified or the date any corresponding cost report is due, if applicable.

ACO's: A Work in Progress

by Mike Segal, Esq., Miami, Florida* and Heather Siegel Miller, Esq., Miami, Florida*

On March 23, 2010, after a year of tumultuous debate, the Patient Protection and Accountable Care Act ("ACA") was signed into law by President Obama.[1] ACA is the most significant legislation regarding healthcare since the passage of the Social Security Act of 1965, which established Medicare. For hospitals and physicians, ACA contains provisions designed to materially change the manner in which healthcare is delivered to Medicare and Medicaid patients and the way healthcare providers are compensated for such services.

ACA authorizes, among other things, that the Centers for Medicare and Medicaid Services ("CMS") create a program that, commencing January 1, 2012, will allow entities called "accountable care organizations," or "ACOs," to share savings obtained by Medicare from the budgeted costs of healthcare services to beneficiaries assigned to those ACOs.[2] ACO has become the latest and hottest "buzz" acronym in the healthcare industry. Yet many healthcare providers and their counsel do not clearly understand what an ACO is, why it is being discussed in every healthcare forum, why there seems to be a new ACO seminar every day and, perhaps most importantly, how one can be created in areas, like Florida, where fee-for-service medicine and independent physicians predominate. This article examines ACOs, discusses why they are a major focus of health reform, what has been learned from other healthcare integration initiatives, and the obstacles that many providers will face in creating an ACO.

ACOs are organizations that integrate a group of healthcare providers with other facilities and members of the healthcare system, to provide care in a collaborative fashion for a defined population of patients. While the exact specifications of an ACO are left to the discretion of the secretary of Department of Health and Human Services ("HHS"), ACOs require a significant amount of primary care physicians, and other physicians. While it is not absolutely necessary, most ACOs will include a hospital. In fact, hospitals will often be the driving force behind an ACO. The primary goal of an ACO - what ACA contemplates - is to control or lower healthcare costs while, at the same time, measurably improving the quality of healthcare. As more succinctly described:[3]

> An ACO is a local health care organization that is accountable for 100 percent of the expenditures and care of a defined population of patients. Depending on the sponsoring organization, an ACO may include primary care physicians, specialists and, typically, hospitals, that work together to provide evidence-based care in a coordinated model. The three major foci of these organizations are:
>
> 1) Organization of all activities and accountability at the local level
>
> 2) Measurement of longitudinal outcomes and costs
>
> 3) Distribution of cost savings to ACO members

Since 1960, healthcare costs in the United States have consistently grown faster than the overall economy and, as a percentage of gross national product ("GDP"), reached 17.3% in 2009. [4]This growth is not sustainable. From time to time there have been attempts to reform healthcare and to control the upward cost spiral. In recent years, experts have proposed using financial incentives to prompt physicians and hospitals to change how they are clinically organized and paid for services in order to improve healthcare quality and efficiency. [5]Recently, the increased ability of healthcare organizations to obtain and utilize meaningful data has made reform potentially more achievable.

Currently, most of the country's healthcare providers are compensated by insurance companies on a fee-for-service basis, which means that healthcare providers are paid for each service that they furnish to a patient. This payment structure has been challenged for many years by the federal government and healthcare "think tanks" as being undesirable. [6]In the 1990s, capitation, where providers offer services based on a set monthly payment per patient, was trumpeted throughout the country as the best way to control healthcare costs. Use of capitation has had checkered results. In most parts of the country its popularity has abated, largely because of the difficulties involved when providers accept risk, and the public perception that capitation means poorer healthcare. However, it may be that capitation, perhaps in a different, more modern and sophisticated dress, is about to make a big comeback under ACA!

During the Bush Administration there were several Medicare demonstration and pilot projects that experimented with modifications and even elimination of fee-for-service remuneration.[7] In fact, managed care plans have already begun to pay physicians for services on the basis of performance – so-called "pay-for-performance" plans[8] – and hospitals have begun sharing cost reductions with physicians through "gain sharing", which, subject to limitations, has been approved by the Office of Inspector General in several published opinions.[9]

In 2009, a Massachusetts Special Commission Report[10] set forth in great detail the case against fee-for-service payments, decrying them as, among other things, rewarding overutilization of services; failing to recognize differences in provider quality or performance; encouraging the use of high-margin services rather than low-cost alternatives; failing to compensate for care coordination; basing payment on market leverage rather than healthcare value; and failing to align provider incentives. In addition, under the current fee-for-service model, healthcare providers are not encouraged to, or financially rewarded for, coordinating the overall care of patients. This often leads to services being duplicated, treatment plans conflicting, and the prescribing of medication being contraindicated. Because of the flaws of the fee-for-service model, reformers of the healthcare system have focused on creating integrated healthcare systems that can work together to manage the overall

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care of a patient. ACA contains many provisions designed to reinforce this movement away from fee-for-service and to compensate ACOs based on quality and efficiency through financial incentives. Critical to the new focus is the ability now, through electronic health records, to create meaningful data to better determine the quality of care being provided.

Over the past decade, the majority of hospital and physician relationships (per-click leases, capitation, joint-ventures, employment arrangements, and under arrangements) were designed primarily to transfer income; physicians needed new sources of income to keep up with the rising costs of their medical practices. Although many of these independent partnerships exist today (and are still being formed), most are not structured with a principal goal to provide quality healthcare at a low cost. Not many healthcare organizations have been able to successfully coordinate the care of patients and improve the quality and efficiency of the healthcare services provided to such patients.

Among the most commonly known collaborative healthcare organizations are Kaiser Permanente, the Mayo Clinic, the Cleveland Clinic and Geisinger Health Systems (collectively we will call these entities the "Integrated Systems"). A major stated goal of each of the Integrated Systems is to allow their healthcare providers to work together to improve the quality of care that they provide to their patients through employing physicians, understanding that a team approach is the cornerstone to providing efficient quality care, creating teams of specialists that collaborate in treating patients, implementing evidence based medicine treatments, and using a comprehensive health information system that integrates an electronic health record with the tools to support physicians in delivering evidence-based medicine.[11] Collaboration and integration between healthcare providers has allowed the Integrated Systems to share patient information and care, including the adoption of evidence based medicine, standards of care performed through the use of clinical protocols.[12] While there have been many efforts to promote integrated healthcare systems, the outcomes achieved by the Integrated Systems has proved difficult to imitate when hospitals and physicians operate independently and try to achieve such integration through capitation, joint ventures, or similar arrangements.

From the success of the Integrated Systems and the failures of those who have tried to imitate them without fully integrating, the ACO emerged as a goal of healthcare reform. The ACO concept began with the observance of the Integrated Systems and networks similar to them where physicians and hospitals would function as a quasi-network and the patients treated within the particular network would stay within it for most of their care. With the acknowledgement that physicians affiliated with, but not necessary employed by, hospitals could work collaboratively in an organized system, President Obama began questioning "why places like the Mayo Clinic in Minnesota, the Cleveland Clinic in Ohio, and other institutions can offer the highest quality care at costs well below the national norm."[13] He further suggested that "we need to learn from their successes and replicate those best practices across our country."[14]

In June 2009, the Medicare Payment Advisory Commission ("MedPAC"), Congress' Medicare-policy advisory arm, identified ACOs as a potential tool for restructuring traditional Medicare coverage to promote care coordination, increase quality and lower cost growth.[15] Under MedPAC's recommendations, ACOs would be comprised of a group of physicians (possibly including a hospital or academic medical center) that would assume the risk of the costs of healthcare provided to Medicare patients and would be compensated through an arrangement that combines traditional fee-for-service payments with financial incentives to reduce costs, improve quality, and achieve greater information transparency.[16] MedPAC indicated that the success of this model would depend on the adoption of clear quality standards combined with a payment methodology that rewards quality while reducing current financial incentives for uncontrolled practice and volume expansion.

However, changing the way providers practice is a daunting task when the underlying structures do not support such change and the cultural differences between physicians and between physicians and hospitals are vast. Collaboration under an ACO model not only requires that hospitals and physicians integrate contractually with a shared sense of purpose, but it also must include a seismic change in culture, which presents a massive

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Immediate past BLSE Chair Joni Armstrong Coffey of Miami visited the Parque Nacional Chiloe, a national park of Chile. Coffey is board certified in city, county and local government law. Former BLSE Chair Michael G. Tanner of Jacksonville, who is board certified in business litigation and civil trial, traveled to Cyprus, the third largest island in the Mediterranean. Robert Sugarman of Coral Gables, who is board certified in labor and employment law, journeyed to Badwater Basin, the lowest elevation point in the Western Hemisphere, in Death Valley National Park, Death Valley, CA.

The flag is available to any certified lawyer who will carry it proudly and send us photos for posting on our Web page. Please contact BLSE consultant Lisa Tipton for more information: 850/561-5769.

challenge and, in any event, seldom occurs quickly. Because the ACO concept is new, its shape and substance will evolve over time as third party payors, hospitals, and physicians learn which model works best. However, it is clear that the success of any ACO will require cultural compatibility between the physicians and the hospitals and shared responsibility for clinical outcomes, financial incentives, and commitment to patient care. The integration between the physicians and hospitals will also need to focus on maximizing outcomes and financial performance associated with shared reimbursement.

Further, with the emergence of the ACO and the focus on how to achieve the best quality outcomes as efficiently as possible, the variations in the structure of an ACO have broadened to include large multi-specialty groups, independent physician associations, and physician hospital organizations ("PHOs"). Regardless of the size or structure of an ACO, ACA provides that an ACO must, among other things:

(a) have a formal legal structure, which includes the ability to receive and distribute payments among its members to promote shared savings;

(b) be able to care for a minimum of 5000 Medicare beneficiaries;

(c) enter into a three year contract with Medicare;

(d) have meaningful primary care participation; and

(e) practice evidence based medicine (i.e. clinical protocols); and have and utilize clinical and administrative systems that allow for reporting on quality and cost measures.[17]

CMS will issue regulations (the "Regulations") that will provide more detailed information regarding the requirements to obtain Medicare certified ACO status. It is currently expected that proposed Regulations will be published on or about mid-January 2011.

Starting in 2013, CMS will begin to withhold 1% of each Medicare MS-DRG payment to fund an incentive pool. CMS will set quality standards, measuring such things as amount of patient readmissions. Top hospital performers relative to their peers may receive more than the hold back, while lower performers may receive less. The withhold will increase to 2% in 2018. Similarly, private payors are following suit with their own "pay-for-performance" models. For hospitals to be able to achieve financial success in this atmosphere, they need to find a way to work collaboratively with their medical staff, especially those who treat patients in the hospital, and will have to tighten controls on the post-acute care facilities where patients are often housed after surgery. It is thought that such actions will result in the best performing hospitals who will be the "winners" in the battle for the withheld funds.

As an ACO, hospitals and their physicians will not just have to perform better, they will have to be transformed and develop a degree of coordination that is currently lacking in healthcare in many parts of the country, including Florida. Physicians generally operate with a high degree of professional autonomy, shying away from being controlled by hospitals or managed care companies, and many will resist partnering with hospitals and accepting responsibility for the care of all patients within a local delivery system. For most hospitals and health systems, payment incentives will have to be synchronized with the changes in the clinical side of the ACO. Much of the desired savings will be achieved by finding ways to keep patients out of the hospital and emergency rooms, and by being proactive to try to keep patients healthy. Primary care physicians, of which there is currently a severe shortage, will need to be the anchor of any ACO and reduce demand for specialists and in-patient services. Patient centered medical homes, where the focus is on proactive treatment of those with chronic diseases like diabetes by primary care physicians and affiliated professionals such as nurses and professional assistants, are being touted by CMS and others as a method of producing better care while controlling or reducing costs.[18]

In some specialties, physicians benefit directly from the volume of services that they perform and the financial incentives offered under ACA may not fully offset the return that these physicians earn from such services. The incentive to constrain utilization and reduce the volume of services will also hinge on whether physicians face similar incentives from private payors. Further, in order for providers to receive the financial incentives, patient outcomes will have to improve, which will require patients to take an active interest in their own care. This can be a challenge when ACA does not require that a patient receive all of his or her care through a particular ACO. Even if all of this can be achieved in a relatively short amount of time, the creation of the technological infrastructure, administrative time, and managerial manpower needed to create and operate an ACO will require significant capital. Therefore, creating a successful ACO from scratch will certainly take time, and probably cannot be achieved by the end of 2011.

In addition to these substantial hurdles, ACOs will have to comply with the federal anti-kickback laws and federal anti-trust laws. Payments within the ACOs could easily be considered a kickback if tied to the volume or value of referrals and powerful ACOs could raise competition issues. ACOs will have to avoid situations where The Centers for Medicare and Medicaid Services ("CMS") might reward an ACO's performance but the Federal Trade Commission ("FTC") hits the same ACO with an antitrust complaint. At an FTC workshop held in Baltimore on October 5, 2010 (the "Workshop"), FTC Chairman Jon Leibowitz announced that the FTC will develop antitrust safe harbors for ACOs, and an expedited review process for ACOs that do not qualify for those safe harbors.[19]

In their joint *Statements of Antitrust Enforcement Policy in Health Care* (August 1996) ("Joint Statements"), the FTC and the Department of Justice set forth the concept that a physician network, even if it is not a single Tax ID/Medicare number group, can share financial healthcare information and jointly bargain with third party payors if the network is "clinically integrated." At Section 8 of the Joint Statements it is stated that clinical integration requires the implementation of:

> ... an active and ongoing program to evaluate and modify practice patterns by the *network's physician*

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> *participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality. This program may include: (1) establishing mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care; (2) selectively choosing network physicians who are likely to further these efficiency objectives; and (3) the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.*[20]

It is likely that the best indication as to what will be contained in the Regulations and the new antitrust safe harbors is contained in three Advisory Opinions issued by the FTC during the past eight years, each effectively concluding that, under the facts presented to it, the network met the definition of "clinical integration." In fact, clinical integration is the key ingredient to a successful ACO, so much can be learned by reading these Advisory Opinions.

The most recent and cogent of the Advisory Opinions, TriState Health Partners, Inc. ("TriState"), issued in April 2009, involved a physician-hospital organization based in Hagerstown, Maryland.[21] TriState was in effect a PHO, a joint venture between a physician network (with a large group of primary care physicians) and a hospital. In a 38 page opinion, the FTC concluded that TriState, "while still in the early stages of development in some respects, appeared to have the potential to create substantial integration among its participants, with the potential to produce significant efficiencies, *including both improved quality and more cost-effective care (italics added)*."

While the discussion of the antitrust regulations in this Advisory Opinion is insightful, in this article our focus is on the manner in which TriState is structured and how it operates, as we believe it may be, in some respects, a guideline as to what will appear in the Regulations. TriState stated that its three major objectives were to: facilitate and assure collaboration among its physician members, in order to improve the health of its patients and the delivery of services "resulting in the right care being rendered in the right setting at the right time;" induce all with a stake in TriState, including physicians, hospitals, case managers, administrators, payors and patients, to engage in a "cohesive and comprehensive program of care management" that would result in better quality of care for patients while lowering costs for payors; and allow TriState to offer a set of integrated services not available otherwise in the marketplace.[22]

The TriState program included the following components, which were viewed favorably by the FTC and are highly likely to be material in creating a Medicare-certified ACO:

- Implementing a sophisticated health information technology system that all of the ACO physicians are required to use;
- Developing clinical practice guidelines and protocols and monitoring physicians to make certain they abide by them;
- Monitoring overutilization and underutilization of services by physicians;
- Developing, implementing, and overseeing policies and procedures related to utilization management, case management and disease management;
- Monitoring the achievement of physician performance targets, using peer, regional and national benchmarks, and making recommendations for both individual and group performance improvements, including report cards, peer counseling, and expulsion; and
- Requiring a financial commitment from each physician.

Each TriState physician was also required to enter into a provider agreement, which requires each physician to:

- Participate in all TriState contracts (no opting out);
- Provide TriState with patient and treatment information deemed necessary to implement the TriState programs;
- Refer patients to other TriState physicians when medically appropriate (note that the allows patients the ability to choose their physicians, whether or not they are part of the ACO);
- Comply with all of TriState's policies, procedures, rules and regulations;
- Be trained in, and use, TriState's health information network;
- Assist TriState in completing quality, safety, and cost assessments; and
- Serve on TriState's clinical integration oversight committees.

It is likely that virtually all of the above will be required under the Regulations for a Medicare-certified ACO.

It would be an understatement to say that there is serious ambiguity and confusion concerning the creation of an ACO, as many of the specific details are currently left to the discretion of HHS. Hopefully, the Regulations, when final, will provide clarity. Meanwhile, providers are gearing up to form ACO collaboratives and raising capital to purchase the technology necessary to achieve reliable, high quality patient care, achieve greater coordination and collaboration in the administrative processes, and create clinical protocols.

At the Workshop, CMS Administrator Donald Berwick stated that the "triple aim" of integrated care is improving individual patient care, improving the health of communities, and lowering the cost of healthcare services without any diminution in quality.[23] The authors believe that, no matter what happens politically to ACA – even if it were to ultimately be repealed – the aims enunciated by Mr. Berwick are here to stay. Having a significant role and impact in an ACO in the future starts with laying the foundation today.

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continued, next page

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ACO'S

from previous page

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Endnotes:

[1] H.R. 3590, 111th Cong. 2009, "Patient Protection and Affordable Care Act," Washington, DC: US Senate, 2009.
[2] *Id.*
[3] Deloitte. Accountable Care Organizations: A new model for sustainable innovations. Jan. 31, 2010. http://www.deloitte.com/assets/Dcom- UnitedStates/Local %20Assets/Documents/US_CHS_AccountableCareOrganizations_070610.pdf
[4] A.M. Sisko, C.J. Truffey, S.P. Keehan, J. A. Posal, M.K. Clemens and A.J. Madison, "National Health Spending Projections: The Estimated Impact of Reform Through 2019," Health Affairs, October 1, 2010. http://content.healthaffairs.org/cgi/content/abstract/29/10/1933
[5] Shortell, Stephen M.; Casalino, Lawrence P., "Health Care Reform Requires Accountable Care Systems", *The Journal of American Medical Association,* July 2, 2008. http://jama.ama-assn.org/cgi/content/extract/300/1/95.
[6] Applewhite, Scott J., "Obama, Overtreatment Drives Health Care Costs", npr.org. http://www.npr.org/templates/story/story.php?storyId=106859968; E. Werner, "Health care issues: Overutilization of care", *The Seattle Times*, Sept. 25, 2009; Landers J., Health Care System Can Ill Afford to Continue With Fee-For-Service," Dallas Morning News. July 21, 2010. http://www.dallasnews.com/sharedcontent/dws/bus/columnists/jlanders/stories/DN-landers_21bus.ART.State.Edition1.3f68e50.html.
[7] Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services, Medicare Demonstrations; http://www.cms.gov/DemoProjectsEvalRpts/MD.
[8] Henley E., "Pay-For-Performance: What can you expect?," *The Journal of Family Practice*. 2005;54(7): 609-612. http://www.jfponline.com/ccp_article.asp?a=1&ref=5407JFP_PracticeAlert; Press Release, Blue Cross BlueShield Association, "Highmark's Pay-For-Performance Program Is Saving Lives And Health Care Dollars," December 8, 2009. http://www.bcbs.com/news/plans/highmarks-pay4-performance-saves-lives-health-care-dollars.html.
[9] *See, e.g.*, OIG Advisory Opinion No. 07-21 (2007); http://oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-21A.pdf; and OIG Advisory Opinion No. 07-22 (2007); http://oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-22A.pdf
[10] Massachusetts Special Commission Special Report: "Recommendations of the Special Commission on Health Care Payment System," July 16, 2007.
[11] *See* V. Fuhrman, Vanessa, "Replicating Cleveland Clinic's Success Poses Major Challenges," *The Wall Street Journal*, July 23, 2009; D. McCarthy, K. Mueller, and J. Wrenn, "Kaiser Permanente: Bridging the Quality Divide with Integrated Practice, Group Accountability, and Health Information Technology," *The Commonwealth Fund,* June 2009 pub. 1278 Vol. 17; "Mayo Clinic: A Model for Service Success," *American Management Association*, Sept. 2008.
[12] *Id.*
[13] The White House Office of the Press Secretary, Text of a Letter from President Obama to Senator Edward M. Kennedy and Senator Max Baucus, June 2, 2009. http://www.whitehouse.gov/the_press_office/Letter-from-President-Obama-to-Chairmen-Edward-M-Kennedy-and-Max-Baucus/
[14] *Id.*
[15] MedPac 2009 Report to Congress: Improving Incentives in the Medicare Program," June 2009. http://www.medpac.gov/chapters/Jun09_Ch02.pdf
[16] Pub. L. 111-148 § 3022 (amendng § 1899 of Title XVIII of the Social Security Act).
[17] H.R. 3590, 111th Cong. 2009, "Patient Protection and Affordable Care Act," Washington, DC: US Senate, 2009.
[18] *See* Mark W. Friedberg, Deborah J. LAi, Peter S. Hussey and Eric C. Schneider, "A Guide to the Medical Home as a Practice-Level Intervention," The American Journal of Managed Care, December 2009. http://www.ajmc.com/supplement/managedcare/2009/A264_09dec_HlthPolicyCurOne/A264_09dec_Friedberg529to299.
[19] Thomas Bartrum, Tracy Weir and Bryan Rockwell, "Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and CMP Laws," American Health Lawyers Association Practice Group Email Alert, October 8, 2010.
[20] U. S. Department of Justice and the Federal Trade Commission, "Statements of Antitrust Enforcement Policy in Health Care (August 1996).
[21] U.S. Federal Trade Commission. Greater Rochester Independent Practice Association, Inc Advisory Opinion (Sept. 17, 2007). http://www.ftc.gov/bc/adops/gripa.pdf; U.S. Federal Trade Commission. MedSouth, Inc Advisory Opinion (Feb. 19, 2002). http://www.ftc.gov/bc/adops/medsouth.shtm; U.S. Federal Trade Commission. TriState Health Partners, Inc. Advisory Opinion (April 13, 2009); http://www.ftc.gov/os/closings/staff/090413tristateaoletter.pdf.
[22] *Id.*
[23] Thomas Bartrum, Tracy Weir and Bryan Rockwell, "Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and CMP Laws," American Health Lawyers Association Practice Group Email Alert, October 8, 2010.

Law Firm Compliance with HIPAA's Ugly Stepsister: The HITECH Act

by Radha V. Bachman, Esq., Tampa, Florida* and Patricia S. Calhoun, Esq., Tampa, Florida*

Key provisions of the Health Information Technology for Economic and Clinical Health Act (HITECH) expand the scope and applicability of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to include the activities of business associates of HIPAA covered entities.

42 USC 17931 Section 13401 – "HITECH"

(a) "Application of Security Provisions, - Sections 164.308, 164.310, 164.312, and 164.316 of title 45, CFR, shall apply to a business associate of a covered entity in the same manner that such sections apply to the covered entity…"

(b) "Application of Civil and Criminal Penalties, - In the case of a business associate that violates any security provision specified in subsection (a), sections 1176 and 1177 of the Social Security Act (42 USC 1320d-5, 1320d-6) shall apply to the business associate with respect to such a violation in the same manner such sections apply to a covered entity that violates such security provision."

HITECH signed into law on February 19, 2009, extended the Security Rule and some portions of the Privacy Rule provisions to business associates.[1] Pre-HITECH, management and disclosures of protected health information (PHI) by a business associate (BA) were governed by an agreement with the covered entity. Therefore, BAs that failed to comply with the terms of their business associate agreements could be subject to contractual liability under a breach of contract theory. Post-HITECH, BAs that fail to comply with the pertinent provisions of HITECH and their business associate agreements continue to be liable to covered entities by way of their contracts but are now also subject to federal enforcement and penalties. Therefore, BAs now have liability exposure for breaches and failures to protect PHI from both the covered entity client and the federal and state governments. Many law firms receive, transmit and store PHI from their covered entity clients in the course of representation. Specific practice areas that may be affected are workers compensation, health care compliance, medical malpractice, insurance defense, labor/employment and products liability.

This article focuses on the unique issues facing law firm - business associates that receive protected health information from their covered entity clients and the methods for achieving compliance under HITECH's new mandates.

What Is Protected By the Security Rule?

Under HITECH, the BA has to implement certain administrative, technical and physical safeguards to protect electronic health information from unauthorized access, alteration, deletion and transmission. "Electronic health information" is defined as individually identifiable health information transmitted by electronic media or maintained in electronic media.[2] Therefore, according to the plain language of HITECH, it seems as if protection of paper records containing PHI would not be subject to the new HITECH requirements for BAs. Such a reading would be short-sighted in light of OCR's interest in increasing, not limiting, the level of regulation in this area. A breach of paper records *may* subject a BA to liability under HITECH based on the following all encompassing paragraph:

> Application of Contract Requirements. - In the case of a business associate … that obtains or creates protected health information pursuant to a written contract … the business associate may use and disclose such protected health information only if such use or disclosure, respectively, is in compliance with each applicable requirement of section 164.504(e) of such title.[3]

Commentators believed, and Department of Health and Human Services, Office of Civil Rights (OCR) recently confirmed, that this provision applies civil and criminal penalties to BAs when BAs disclose PHI (in any form) in a way that breaches their business associate agreements.[4] This same section also applies several new Privacy Rule provisions enacted under HITECH to BAs.

What Is Required By the Security Rule?

The first step to achieving compliance with the Security Rule is the appointment of a Security Officer.[5] The Security Officer can be the same individual acting as the Privacy Officer, as required by the Privacy Rule, but the Security Officer will also be responsible for developing and implementing the policies and procedures more fully discussed below. Smaller firms may decide to appoint a single Security Officer to perform the functions necessary to implement, monitor and supervise compliance with HIPAA and HITECH. However, some larger organizations may find it useful to create a "team" of individuals who will work side-by-side with the Security Officer to ensure compliance.

The second, and arguably the most important, step is the completion of a risk assessment.[6] The risk assessment forces BAs to assess their size, complexity, capabilities, technical infrastructure, hardware, software security capabilities, costs of the security measures and the probability and criticality of potential risks to electronic protected health information ("ePHI") for purposes of identifying those security measures that can be reasonably and appropriately implemented. Some questions a firm may ask itself while conducting a risk assessment are: (1) Does the firm have complete and current formal instructions for reporting security breaches including documentation of reporting procedures and response procedures entity-wide? Do they include formal written mechanisms

continued, next page

to document security incidents?, (2) Are written formal procedures that establish and maintain personnel security in place and current? And, (3) Does the firm maintain a record of the transport and movement of hardware, software, and electronic media? Risk management requires the BA to implement security measures that are appropriate and reasonable based on the risk assessment. An important issue for law firms and attorneys is the widespread use of Blackberry or similar hardware in which attorneys and staff are able to receive work-related e-mail correspondence to handheld devices. Often times, depending on the nature of the legal work being performed, this correspondence may contain PHI. The mere fact that it is being transported and stored in an electronic medium makes it subject to HITECH and the Security Rule. Research in Motion, the creator of the Blackberry, has issued guidance stating that its handheld technology is not inherently "HIPAA-compliant." Rather, users must take affirmative steps to protect information contained on these devices through password protection, remote data wiping and encryption. Many commentators have suggested that transmitting PHI *from* a Blackberry is not protected because of the technology's use of various outbound servers. Law firms will want to review policies related to employee use of Blackberries or similar hardware and consider requiring all users to password protect their devices.

It is important to note that the Security Rule recognizes that all measures are not appropriate or reasonable for all entities and therefore categorizes certain measures as "Required" or "Addressable." The "required" implementation specifications must be implemented. The "addressable" designation permits covered entities to determine whether the addressable implementation specification is reasonable and appropriate for that covered entity. If it is not, the Security Rule allows the covered entity to adopt an alternative measure that achieves the purpose of the standard, if the alternative measure is reasonable and appropriate.[7] An organization should thoroughly review these standards in connection with its risk assessment and document its analysis related to each particular specification.

Once the risk assessment is complete, the next required step to achieving compliance with the Security Rule is creating and then maintaining a robust set of policies and procedures related to PHI.[8] These policies and procedures should be all-inclusive and include information regarding: handling of employees who fail to comply with the BAs policies and procedures; specific instructions on password protecting electronic media; disaster recovery and emergency mode operation and backup planning; workstation security; user identification protocols; review of electronic media usage and device disposal and reuse. Law firms that consistently receive and process PHI may already have a set of policies and procedures in place. However, in light of HITECH's new enforcement scheme, even firms that only have occasional contact with PHI must consider the benefits of adopting and implementing similar policies.

History tells us that employee lack of knowledge and misinterpretations of the pertinent regulations are the biggest contributors to unauthorized access and disclosures of PHI. Therefore, it is not surprising that training is another required measure. Training sessions on the new requirements should be provided to all employees who have access to PHI on a regular basis and new hires should receive training at commencement of employment. All training provided by a firm should be documented by the Security Officer in a central place that can be easily accessed in the event of an OCR investigation.

Breach Notification

This article will not delve into the specifics regarding the new breach notification rules set forth in HITECH.[9] However, it is important to note that the OCR has promulgated rules which create a safe harbor for encrypted information. The rules state that encryption and destruction are the only two methods for rendering PHI un-unuseable, unreadable, or indecipherable –providing for "safe harbors" under the notification requirements.[10] Therefore, while the encryption of information systems, and other expensive devices such as cross-cut shredders, are not *required* technical safeguard specifications, law firms will want to weigh the cost of incorporating these technologies into their businesses as a form of long-term insurance against the costs and liability that they may face in the event of a large-scale breach. Likewise, law firms will want to carefully review any post-HITECH business associate agreements presented to them by their covered entity clients to ensure that encryption is not a safeguard required pursuant to those agreements. OCR has been presented with a number of obstacles as they try to fit the new HITECH requirements into the current HIPAA regulatory framework. A prime example of this is OCR's late July withdrawal of its own final rule proposal from Office of Management Budget review.[11] Commentators have suggested that the withdrawal is either due to reported breaches clogging the system or the ongoing argument regarding the "risk of harm" standard. Either way, OCR has commented that a new and improved final rule should be issued in the coming months.

Accounting of Disclosures

HITECH also expanded the scope of a covered entity (and now) BA's responsibility to account for disclosures of PHI. Pre-HITECH, disclosures made in the course of treatment, payment and health care operations were not required to be tracked. HITECH changed that, now permitting patients to request these types of disclosures through an EHR and requiring covered entities and, in some cases, BAs to provide the requested information.[12] The new provision allows covered entities to include disclosures made by BAs in the accounting report they develop for the requesting patient, or they can pass the ball and provide patients with a list (including contact information) for BAs involved in disclosing PHI and direct patients to request the accounting directly from the BA. Many commentators have called the new accounting requirements a logistical nightmare and have urged Congress to reconsider its position. With the expanding use of EHR systems by covered entities, accounting for disclosures made using these systems may not prove to be as practically difficult for those organizations. The burden, therefore, lies on the

continued, next page

THE HITECH ACT

from previous page

BAs who may not possess adequate technology to track disclosures.

Law firms should be prepared to begin receiving and responding to such requests when the future accounting requirements become reality. An important step is the creation of a database to ensure all uses and disclosures are tracked. In the May 3, 2010, Federal Register posting, OCR requested assistance in crafting a proposed rule on the accounting of disclosures requirement.[13] The deadline for comments was May 18, 2010. We anticipate that OCR will issue a proposed rule with respect to accountings soon.

HIPAA Enforcement

HITECH includes a number of changes to HIPAA's enforcement provisions. Namely, Sections 13401 and 13404 provide that BAs can be held directly liable by state and federal authorities for failure to comply with the applicable standards. HITECH also contains a clarification to a previously debated issue: individual liability under HIPAA. Section 13409 provides that HIPAA's criminal penalties can be enforced against individuals, including, but not limited to, employees of a covered entity. Based on language contained in the Proposed Rule, as discussed in detail below, the same may apply to employees of BAs.

The HITECH enforcement scheme also gives HIPAA enforcement power to state attorneys general providing that a state's chief legal officer may pursue civil HIPAA violations in cases where criminal penalties could attach but the federal government has decided not to pursue the case. Finally, the Proposed Rule emphasizes that in addition to having direct liability for civil monetary penalties for impermissible uses and disclosures of PHI, BAs are still contractually liable to covered entities pursuant to their BA contracts.

OCR Notice of Proposed Rulemaking

After much anticipation, OCR, on July 14, 2010, published a Notice of Proposed Rulemaking (Proposed Rule) that proposes significant revisions to the HIPAA Privacy, Security and Enforcement rules in light of HITECH.

The Proposed Rule would expand the definition of "business associate" to apply to entities that create or receive PHI for the covered entity. The OCR specifically identifies document management companies as possible BAs. In its most significant modification, the Proposed Rule provides that subcontractors of a BA are also defined as "business associates". The Proposed Rule applies to any agent or other person who acts on behalf of a BA in handling PHI, *even if no contract between the parties exists*. In light of the potential liability for BAs, executing a BA agreement with subcontractors may be recommended since the BAs would have the responsibility to ensure that their subcontractors are protecting the security of ePHI. Following that logic, subcontractors may in turn be required to obtain BA agreements with the parties with which they contract for services that provide access to PHI. OCR clarifies its position that direct liability attaches, regardless of whether the BA and its subcontractor have entered into a BA agreement.

The Proposed Rule also revises the definition of "workforce member" clarifying that employees, volunteers, trainees, and other persons whose conduct in the performance of work for a BA is under the direct control of the BA, may be held liable for a HIPAA violation. This provision significantly impacts the attorneys, paralegals, and administrative personnel working in law firms that are BAs of covered entity clients.

The Proposed Rule revises the BA contract provisions to require that: (1) BAs comply, where applicable, with the Security Rule with regard to electronic PHI; (2) BAs report breaches of unsecured PHI to covered entities; and (3) BAs ensure that any subcontractors that create or receive PHI on behalf of the BA agree to the same restrictions and conditions that apply to the BA with respect to such information. Similar to the requirements now in place for covered entities, in the event that a BA becomes aware of noncompliance by its subcontractor, it must take reasonable steps to cure the breach and, if such steps are unsuccessful, terminate the contract, if feasible.

With respect to the timeline for compliance, the Proposed Rule includes a provision to grandfather certain existing BA contracts for a specified period of time. The Proposed Rule adds transition provisions to allow covered entities and BAs (including subcontractors) to continue to operate under certain existing contracts for up to one year beyond the compliance date of an OCR-issued final rule on the matter. OCR proposes to deem such contracts to be compliant with the modifications in the final rule

continued, next page

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until either the covered entities or BA has renewed or modified the contract following the compliance date of the modifications, or until the date that is one year after the compliance date, whichever is sooner.

OCR is soliciting comments on the Proposed Rule, which may be submitted on or before September 13, 2010.

Bar Association Action

At the time HIPAA was initially enacted, members of the American Health Lawyers Association's (AHLA) Health Information Technology section penned a letter to the then acting Director of the OCR, Richard Campanelli. The letter requested clarification regarding a number of HIPAA-applicability issues specific to attorneys and law firm. Specific inquiries were made regarding a lawyer-BAs responsibility to: (1) track disclosures, (2) enter into agency agreements with experts, court reporters and other litigation support personnel and, (3) comply with the minimum necessary of a covered entity client. The OCR appeared to give some credence to the letter and the questions contained therein as it ultimately responded to the letter through the frequently asked questions section of its website. An important issue for BA-law firms is the responsibility to report covered entity-clients that the BA knows has committed a violation in light of the HITECH termination rule and the related ethical issues involved in doing so.[14] As of the date of this article, we have not received information regarding similar action by the AHLA with respect to HITECH, lawyers and law firms.

Similarly, the American Bar Association has successfully challenged the federal government's characterization of lawyer as "creditors" for purposes of both the Fair and Accurate Credit Transactions Act and Gramm-Leach-Bliley. Lawyers have a knack for questioning the applicability of federal regulations to their profession and it remains to be seen whether issuance of a BA final rule by the OCR may finally provoke attorneys and related professionals to challenge the practical application of HITECH to the legal profession.

Conclusion

The passage of HITECH has and will continue to create many challenges for not only HIPAA covered entities and their business associates, but also third party contracting entities that may receive PHI from one of the above. The biggest challenge to date, however, has been the integration of HITECH specifics into HIPAA current law. As the regulator for all HIPAA related issues post-HITECH, OCR has imposed on itself a great burden to incorporate these regulations into a feasible framework that protects both patient privacy without creating an unreasonable burden on covered entities and BAs.[15] Despite the perceived delay in adopting the necessary components for effective administration of HITECH, law firms that serve health care providers and other covered entity clients should be in the process of incorporating the requirements set forth in the Security Rule and evaluating the relevance and necessity of pursuing other available options for protecting PHI held by the organization. Further, law firms should thoroughly evaluate whether the services being provided to covered entity clients even rises to the level of business associate services subject to HIPAA and HITECH. The federal government's path to achieving 100% data security is becoming increasingly rigid and the push for enforcement mounting exponentially. If your firm has put off taking the necessary (and often expensive) measures to ensure HITECH compliance, the clock is ticking - and you may be running out of time.

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Endnotes:

[1] HITECH Act, § 13401
[2] 45 C.F.R. §160.103.
[3] HITECH ACT, §13404
[4] 75 Federal Register 134 (July 14, 2010)
[5] *See* 45 C.F.R. §164.308(2)
[6] *See* 45 C.F.R. §164.308(1)(ii)(A)
[7] 45 C.F.R. § 164.306(d)
[8] *See* 45 C.F.R. §164.308, 310, 312
[9] For a thorough analysis of the new breach notification requirements, see Spring 2010 Health Law Section Newsletter article entitled, "Breach Notification Requirements for the Improper Use or Disclosure of Unsecured Protected Health Information".
[10] 74 Federal Register 42744 (August 24, 2009)
[11] *See* 74 Federal Register 42744 (August 24, 2009). *See http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/finalruleupdate.html*
[12] HITECH Act, §13405(c)
[13] 75 Federal Register 84 (May 3, 2010)
[14] *See* 45 C.F.R. § 164.504(e)(1)(ii)
[15] In August 2009, HHS Secretary Kathleen Sebelius delegated the responsibility for administration and enforcement of the HIPAA Security Rule to the Office of Civil Rights, the Department of Health and Human Services. Previously, the Center for Medicare and Medicaid Services was responsible for administration of the HIPAA Security Rule.

Medical Staff Credentialing: Responsibility and Liability of Hospital Boards

by Nicholas W. Romanello, Esq., West Palm Beach, Florida*

The hospital's newest board member enters the board room while the CEO nervously chats up other board members. The new board member is well known to her colleagues. A community leader with long ties to the hospital, she has donated a significant amount of time and resources towards the development of the hospital. Like most of the other hospital board members, Ms. Newmember does not have a medical background. After the meeting is opened and pleasantries exchanged, the CEO announces that the first order of business is to "credential" six new members to the medical staff and "re-credential" nine members to the medical staff. It is at this point that Ms. Newmember realizes she isn't in Kansas anymore.

Credentialing is the generic term used to generally describe the process by which a hospital determines the eligibility of a physician or other allied health professional to join its medical staff as well as the scope of such services a provider may render in light of the applicants medical education, training and experience.

Most contemporary hospitals have a well developed process which typically works as follows:

• The hospital board and the medical staff design and implement medical staff bylaws which establish the policies, rules and procedures used in determining one's eligibility for medical staff privileges.

• Physicians and other allied health professional apply or are invited to apply for medical staff privileges thus triggering the policies, rules and procedures for credentialing as set forth in the medical staff bylaws.

• Upon receipt of an application for medical staff privileges is received by the hospital credentialing verification or due diligence process is initiated by hospital management.

• Upon completion of the staff driven due diligence process, the medical staff (most commonly the medical executive committee) completes a review of the application and makes a recommendation to the hospital's governing board.

• Finally, the hospital board approves of the appointment of the applicant to the medical staff with a specific delineation of privileges.[1]

It is this last step – the appointment of an applicant to the medical staff along with a delineation of privileges which causes board members so much consternation. Board members who are most likely paid little, if anything, for their dedicated service to the hospital. Board members, like Ms. Newmember, who while community business, social and political leaders may have very little experience in healthcare administration. Board members who have been orientated, trained and maybe a little intimidated by issues such as corporate compliance, fiduciary duties and liability and want nothing more than to do what is right for their hospital. These ultimate decision makers who rely heavily upon staff for guidance on credentialing issues are frequently asking about their own responsibility and potential liability when it comes to credentialing. This note briefly outlines the roles and responsibilities hospital board members have in credentialing physicians and allied health professionals.

Hospital Governance

Section 395.0191(5), Florida Statutes (2010), directs that the "governing board of each licensed facility shall set standards and procedures to be applied by the licensed facility and its medical staff in considering and acting upon applications for staff membership or clinical privileges…" In order to comply with the statutory mandate, the governing board bylaws customarily include a provision which specifies the board's authority to appoint, re-appoint, credential and discipline the medical staff of the hospital.

The hospital board has an indispensible partner in the credentialing process – the hospital's medical staff. Traditionally, hospital medical staffs are organized into a formal structure that appoint or elect members to a Medical Executive Committee (MEC). While each hospital's governance structure will differ, the purpose and responsibility of the MEC is to govern the professional activities of its members and serve as the primary means for accountability to the governing board concerning such professional activity through, in part, the delineation of clinical privilege. Medical staff bylaws usually provide for the basic qualifications and conditions of staff membership, procedures for appointment and reappointment, and modification in staff category and clinical privileges.

While practices vary from facility to facility, the process by which an applicant is "credentialed" typically entails a verification of the applicant's medical education, training and experience followed by a recommendation by the MEC to appoint or reappoint the applicant. The governing board then acts upon the MEC's recommendations by either approving or rejecting the appointment or reappointment of an applicant to the hospital's medical staff.

The Joint Commission

Founded in 1951, the Joint Commission ("TJC") seeks to continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value.[2] Today TJC accredits approximately 18,000 healthcare organizations and programs in the United States. TJC has accredited hospitals for more than 50 years and today it accredits approximately 4,250 general, children's, long term acute, psychiatric, rehabilitation and surgical specialty hospitals, and 358 critical access hospitals, through a separate accreditation program. Approximately 88 percent of the nation's hospitals are currently accredited by TJC.[3]

continued, next page

CREDENTIALING

from previous page

Hospitals seek Joint Commission accreditation because, in large part, it provides deeming authority for Medicare certification. From 1965 through 2008, federal law provided that a Joint Commission accredited hospital was deemed to meet virtually all Medicare Conditions of Participation where the accredited hospital authorizes the release of the most current accreditation survey to the Department of Health and Human Services. The enactment of the Medicare Improvements for Patients and Providers Act of 2008 required TJC to apply to the Centers for Medicare and Medicaid Services (CMS) for hospital deeming authority. On November 27, 2009, CMS approved the continuing deeming authority for TJC through July 15, 2014.[4] TJC accreditation is customarily valid for up to 3 years.

The current Joint Commission manual contains at least 2 standards[5] which impose credentialing responsibilities upon the GRASB.

First, Standard MS.06.01.01 requires "[t]he hospital [to] collect information regarding each practitioner's current license status, training, experience, competence, and ability to perform the requested privilege." TJC examines this standard through, in part, Elements of Performance[6] - MS.06.01.03 (A) (3) which determines whether "[t]he credentialing process is approved by the governing body."

Additionally, Standard MS.06.01.07 states "[t]he organized medical staff reviews and analyzes all relevant information regarding each requesting practitioner's current licensure status, training, experience, current competency, and the ability to perform the requested privilege. This standard is surveyed, in part, by the following two elements of performance:

> MS.06.01.07(A)(2) "The hospital, based on recommendations by the organized medical staff and approved by the governing board, develop criteria that will be considered in the decision to grant, limit or deny requested privileges."
>
> MS.06.01.07 (A) (8) "The governing body or delegated body committee has final authority for granting, renewing, or deny privileges. (See also MS.01.01.01, EP 17)"

In order to maintain accreditation by TJC and, by way of deeming authority, Medicare Conditions of Participation hospitals must maintain a robust credentialing process which culminates with the governing board making a final determination on staff appointments.

Florida Law

Responsibility

As set forth more fully above, Florida law requires the governing board of a hospital to set standards and procedures to be applied by the hospital and its medical staff in considering and acting upon applications for staff membership or clinical privileges.[7] Additionally, "[a] medical review committee of a hospital … shall screen, evaluate, and review the professional and medical competence of applicants to, and members of, medical staff.[8] Thus, attorneys representing hospital boards must appreciate that Florida law is clear that that Hospital Boards have final approval of medical staff membership and privileges.[9] In other words, Ms. Newmember and her colleagues enjoy the ultimate responsibility for appointing members of the hospital medical staff.

Liability

With Ms. Newmembers newfound responsibility for appointing members of the hospital's medical staff comes the corresponding liability for such activities. As an attorney representing hospitals, it is imperative that you advise your board member clients about the potential liability associated with medical staff appointments. Hospital board liability for credentialing may come in one of the following two forms:

1. from applicants to and members of the Hospital's medical staff, and

2. from Hospital patients.

Claims by Aggrieved Physicians

While outpatient facilities such as ambulatory surgical centers continue to proliferate across Florida, most surgeons continue to rely upon their relationship with hospitals as their primary means to maintain a livelihood. Likewise, hospital-based practitioners (radiologists, anesthesiologists, pathologists and emergency department physicians) may rely exclusively upon their medical staff appointment to provide a location for the delivery of their services. With so much depending upon a medical staff appointment, physicians may resort to litigation to ensure an appointment or re-appointment. Healthcare trade publications and listserves do a fantastic job of chronicling credentialing these disputes (and suits) between physicians and hospitals.

Under Florida law, a physician does not enjoy a vested right to hospital staff privileges.[10] Likewise, physicians do not enjoy an organic right to medical staff membership in a public hospital.[11] However, Florida has adopted the majority view that medical staff bylaws constitute a binding and enforceable contract between a hospital and members of the medical staff.[12] As such, applicants to and members of the medical staff do enjoy potential claims against a hospital for failure to grant or renew medical staff privileges. These claims usually sound in breach of contract and fraud and seek to enjoin the hospital from refusing to appoint or reappoint a practitioner.[13]

Despite the risks associated with this exposure, Florida law provides for immunity to any member of a hospital's governing board for any action arising out or related to the execution of their medical staff responsibilities – absent intentional fraud.[14] Likewise, while outside the scope of this opinion, the Health Care Quality Improvement Act (HCQIA)[15] provides similar immunity from monetary damages against a professional review body. Finally, as it relates to public facilities, Florida's limited waiver of sovereign immunity may serve to limit the potential damages against members of a public hospital board.[16]

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Corporate Negligence Doctrine

Patients have an expectation that physicians who treat them while in a hospital have the requisite education, training and experience to provide those in-patient services necessary to medically manage them. Patients may also assume that the hospital itself serves as the arbiter as to which physicians maintain the requisite background to provide in-patient services. Following an untoward event in the hospital, a patient may, as part of a medical malpractice claim, argue that the hospital failed to exercise the appropriate level of due diligence in credentialing a specific physician. Moreover, some patient will allege that the hospital's "negligent credentialing" of a physician was the direct and proximate cause of their injuries.

The State of Florida is among at least twenty (20) states[17] in the country which recognize the corporate negligence doctrine as it relates to the credentialing of physicians by a hospital.[18] It is axiomatic that hospitals owe a duty of care to their patients to ensure that only competent physicians are granted staff privileges. A hospital runs the risk of breaching this duty where it admits a physician to the medical staff without properly verifying his credentials. Florida law is such that, as a matter of public policy, hospitals are in the best position to protect their patients and, consequently, have an independent duty to select and retain competent independent physicians seeking staff privileges. The hospital's liability extends only to the physician's conduct while rendering treatment to patients in the hospital and does not extend to his conduct beyond the hospital premises. Moreover, the hospital will only be responsible for the negligence of an independent physician when it has failed to exercise due care in the selection and retention of that physician on its staff.

Attorneys representing hospitals are strongly encouraged to familiarize themselves with their hospital client's credential verification and due diligence process in order to counsel board members on the corporate negligence doctrine.

Conclusions

Serving as a hospital board member is an exciting and rewarding way for individuals to give something back to their community. Hospital board members typically have the best of intentions while exercising their governance authorities – including appointing and reappointing members of the hospital's medical staff. Attorneys who limit their practice to healthcare related issues are strongly encouraged to advise their board member clients that Florida law and TJC impose the duty to "credential" members of the medical staff upon the governing board. Credentialing physicians, as with any duty, comes with potential liability if performed inappropriately. Educating our clients on the duties, responsibilities and immunities surrounding the credentialing process will enhance the medical staff appointment process by enabling hospital board members to perform these functions with full knowledge of their legal obligations and consequences. What better way for a healthcare attorney to demonstrate her value than by spending an hour explaining these issues with Ms. Newmember.

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Endnotes:

[1] Greeley, Hugh P., *Credentialing, Part One: the Patient, Medical Leadership Institute 2009.*

[2] Facts about The Joint Commission. (August 23, 2010). Retrieved from http://www.jointcommission.org/AboutUs/Fact_Sheets/joint_commission_facts.htm.

[3] Facts about Hospital Accreditation. (January 15, 2010). Retrieved from http://www.jointcommission.org/AccreditationPrograms/Hospitals/hospital_facts.htm.

[4] 42 U.S.C. §§ 1395bb.

[5] Joint Commission standards are "statements that define the performance expectations and/or structures or processes that must be in place for [a hospital] to provide safe, quality care, treatment and services." *Comprehensive Accreditation Manual for Hospitals: The Official Handbook, CAMH Update 2, October 2009 p. HM-2.*

[6] Joint Commission Elements of Performance (EPs) are "statements that detail the specific performance expectations and/or structures or processes that must be in place in order for an organization to provide quality care, treatment, and services. EPs are scored and determine a hospital's overall compliance with a standard." *Comprehensive Accreditation Manual for Hospitals: The Official Handbook, CAMH Update 2, October 2009 p. HM-2.*

[7] Section 395.0191(5), Florida Statutes (2009).

[8] Section 766.110(2). Florida Statutes (2009).

[9] Florida Administrative Code 59A-3.272.

[10] *West Coast Hosp. Ass'n v. Hoare*, 64 So. 2d 293 (Fla. 1953).

[11] *Taylor v. Horn*, 189 So. 2d 198 (Fla. 2d DCA 1966).

[12] See, *University Community Hospital, Inc. v. Wilson*, 1 So. 2d 206, 212 (Fla. 2d DCA 2008).

[13] See generally, *Naples Community Hospital v. Hussey*, 918 So. 2d 323 (Fla. 2d DCA 2005).

[14] Section 395.0191(7), Florida Statutes (2009).

[15] 42 U.S.C. § 11101.

[16] See, Section 768.28, Florida Statutes (2010).

[17] *See e.g., Larson v. Wasemiller*, 738 N.W. 2d 300, 313 (Minn. 2007); *See, e.g., Gahm v. Thomas Jefferson University Hospital, et al.*, 2000 U.S. Dist. 2072 (E.D. Pa. 2000) ("Hospital may be held liable under the doctrine of corporate negligence." *citing Thompson v. Nason Hospital*, 591 P.2d 703 (1991)); *Bryant v. McCord*, et al., 1999 Tenn. App. LEXIS 26 *26 (Tenn. Ct. App. 1999); *Eckhart v. Charter Hospital of Albuquerque, Inc.*, 953 P.2d 722, 732 (N.M. Ct. App. 1997); *Domingo v. Queen's Medical Center, et al.*, 985 F. Supp. 1241, 1245 (D. Haw. 1997) (holding that "a hospital has a duty to ensure that it only grants hospital privileges to competent physicians. . . ."); *Clark v. Southview Hospital & Family Health Center*, 628 N.E.2d 46 (Ohio 1994); *Strickland v. Madden*, 448 S.E.2d 581, 586 (S.C. Ct. App. 1994); *Rodrigues v. Miriam Hospital*, 623 A.2d 456, 462 (R.I. 1993); *Albain v. Flower Hospital*, N.E.2d 1038, 1045 (Ohio 1990), *rev'd on other grounds*; *Insinga v. LaBella*, 543 So. 2d 209, 211 (Fla. 1989); *Blanton v. Moses H. Cone Memorial Hospital, Inc.*, 354 S.E.2d 455, 457-58 (N.C. 1987); *Park North General Hospital v. Hickman*, 703 S.W.2d 262, 266 (Tex. Ct. App. 1985); *Raschel v. Rish*, 488 N.Y.S. 2d 923, 925 (N.Y. App. Div. 1985), *aff'd* 504 N.E.2d 389 (N.Y. 1986); *Benedict v. St. Luke's Hospital*, 365 N.W.2d 499, 504 (N.D. 1985); *Pedroza v. Bryant*, 677 P.2d 166, 170 (Wash. 1984) (en banc); *Elam v. College Park Hospital*, 132 Cal. App. 3d 332 (Cal. Ct. App. 1982); *Johnson v. Misericordia Community Hospital*, 301 N.W.2d 156, 164 (Wisc. 1981); *Kotto v. Gilbert*, 570 P.2d 544, 550 (Colo. Ct. App. 1977); *Utter v. United Hospital Center, Inc.*, 236 S.E.2d 213, 215 (W. Va. 1977); *Ferguson v. Gonyaw*, 236 N.W.2d 543, 550 (Mich. Ct. App. 1975); *Corleto v. Shore Memorial Hospital*, 350 A.2d 534, 538 (N.J. 1975); *Mitchell County Hospital Authority v. Joiner*, 189 S.E.2d 412, 414 (Ga. 1972); *Purcell v. Zimbelman*, 500 P.2d 335 (Ariz. Ct. App. 1972); *Gridley v. Johnson*, 476 S.W.2d 475, 484-85 (Mo. 1972); *Foley v. Bishop Clarkson Memorial Hospital*, 173 N.W.2d 881, 884 (Neb. 1970).

[18] *Insinga v. LaBella*, 543 So. 2d 209 (Fla. 1989).

Medicare Revocation of Provider Status – The Newest Threat to Medicare Providers

by Lester J. Perling, Esq., Fort Lauderdale, Florida*

Medicare-enrolled providers and suppliers are increasingly the victims of unwarranted revocations of their Medicare provider status. A movement toward Medicare enrollment revocation based on alleged non-compliance with either requests for revalidation or as a result of site verification visits has emerged. Upon revocation of provider status, providers will not be reimbursed by the Medicare program for services furnished to Medicare beneficiaries as of the effective date of the revocation, which can be retroactive. Revocation of a provider's Medicare billing privileges can effectively terminate a provider's practice.

Revalidations

Beginning in 2009 the Centers for Medicare & Medicaid Services ("CMS") began sending requests for revalidation to Part B suppliers. Revalidation is the process by which CMS or its contractor requires a provider to certify the accuracy of its existing enrollment information with Medicare. A revalidation request requires a provider or supplier to complete the relevant CMS-855 Medicare Enrollment Application form and CMS-588 Electronic Funds Transfer Authorization Agreement form. Recent revalidation requests are intended to facilitate the entry of the provider's enrollment information into the Medicare Provider Enrollment, Chain, and Ownership System ("PECOS"). As part of CMS' PECOS initiative, an ordering or referring provider must be enrolled in the online database by January 1, 2011, to receive reimbursement for services provided to Medicare beneficiaries.

In its effort to enroll providers in PECOS, CMS sent revalidation request letters requesting that practitioners revalidate the enrollment information submitted on their original or most recent CMS-855 forms. CMS haphazardly sent the letters by mass mailing. For example, CMS sent revalidation requests to physical addresses that did not have mailboxes to receive mail and to practitioners' prior addresses. Additionally, CMS did not review addresses for changes and did not address practices by name. Lastly, CMS did not send the letters by certified mail and assumed providers received them. As a result of CMS's carelessness, many practitioners did not receive revalidation request letters.

Providers who *did not receive* revalidation requests had their Medicare status revoked for failing to complete CMS 855 and 588 forms within 60 days from the date of the revalidation request. Practitioners were barred from re-enrollment in the Medicare program for at least one year beginning on the date the notice of revocation was received. Moreover, practitioners were only given an opportunity to submit corrective action plans ("CAP") and/or requests for reconsideration *after* revocation.

Site Verifications

As part of its fraud-prevention initiative, CMS is performing site verifications, resulting in more revocations based on alleged non-compliance with Medicare requirements. Site verifications confirm that Medicare providers are operational and in compliance with Medicare requirements. If the Medicare administrative or zone program integrity contractor's ("MAC") site survey reveals the practice site is closed or not in compliance, the provider's Medicare provider number is revoked retroactive to the date of the site verification visit or possibly earlier if it is determined that non-compliance first occurred on an earlier date. This may lead to a precarious situation because notice of revocation may not be given to the provider for months. As a result, providers may continue treating Medicare patients with the expectation of reimbursement for a significant period of time, not knowing they will be forced to forfeit income when revocation is applied retroactively.

Additionally, some revocations appear to be based on CMS' carelessness. For example, CMS revoked a provider's enrollment status where a practice location had been closed for *six* years, indicating CMS failed to update its own records. Moreover, site verification re-enrollment bars can last as long as two to three years.

When enrollment status is revoked after a site verification visit, the provider may submit a CAP and/or request for reconsideration only *after* revocation has occurred, although in some situations providers should be given an opportunity to submit a CAP *before* revocation, according to federal regulations.

Corrective Action Plans and Reconsideration

A practitioner may submit a CAP and/or request for reconsideration after receiving a revocation notice. A CAP outlines how a provider will bring itself into conformity with Medicare requirements. A request for reconsideration, on the other hand, contends that revocation was erroneous, or if the provider is reinstated as a result of the CAP, the effective date or the reinstatement is incorrect. After receiving a revocation notice letter, a practitioner has 30 days to submit a CAP and 60 days to submit a request for reconsideration. Practitioners should submit CAPs and requests for consideration contemporaneously because a reconsideration request *must be submitted 60 days from the date of the revocation letter,* ***not*** *the date the CAP was denied, which will likely be more than 60 days from the date of revocation.*

Corrective Action Plan

As part of the CAP, a provider must: (1) submit a signed letter explaining why revocation occurred and what efforts will be used to achieve compliance; (2) submit a signed statement that the provider understands how accurate provider enrollment information is supplied; and (3) possibly submit a new CMS-855 form.

There is no appeal from a denied

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MEDICARE REVOCATION

from previous page

CAP. The only available form of relief is the submission of a Request for Reconsideration. If the CAP is accepted, the revocation is rescinded and the practitioner's billing rights are either restored as of the date that CMS determines the provider became compliant or back to the revocation's original effective date.

Notably, a CAP will not be approved until CMS determines the provider is compliant. This will usually require a site visit. The purpose of the site visit is to ensure implementation of the CAP and overall compliance with Medicare's requirements relevant for the provider type.

Request for Reconsideration

A Request for Reconsideration will only be successful if the provider can prove the basis for the initial revocation was erroneous or that CMS did not follow required procedures, such as it sent a notice to the wrong address. Unlike a CAP, a reconsideration is a legal process in that legal arguments can be raised with regard to the lawfulness of the revocation. Providers may appeal denied reconsiderations to an administrative law judge, then the Medicare Departmental Appeals Board, and finally into the courts. It is unclear if practitioners can use reconsideration to resolve problems that caused CAP denial.

Conclusion

Revocation letters have devastating consequences for the providers receiving them because Medicare payments are being halted until the CAP or reconsideration process is complete. Therefore, practitioners are in a state of limbo until the process is sorted out, which can take up to, if not more than, 90 days. CMS' new punitive process is not only harming providers, but hurting patients whose medical care may be delayed by a provider's decision to not risk treating Medicare patients until reinstated. The harsh consequences that providers and their patients are facing are not equivalent to the alleged violations committed.

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Aggravated Identity Theft Statute as a New Prosecutorial Tool Against Health Care Fraud

by Kevin J. Darken, Esq., Tampa, Florida*

Federal prosecutors are starting to use a new weapon in their ongoing battle against health care fraud--the aggravated identity theft statute, 18 U.S.C. §1028A. The reason: Violations of §1028A carry a mandatory minimum two year prison sentence which must be run consecutively to any sentence for an underlying fraud offense. The result is that the stakes for health care providers facing criminal investigations have become much higher.

Elements of Aggravated Identity Theft

Section §1028A punishes any person who "during and in relation" to an enumerated felony crime "knowingly transfers, possesses, or uses, without lawful authority, a means of identification of another person". "Means of identification" is defined in §1028(d)(7) as "any name or number that may be used, alone or in conjunction with any other information, to identify a specific individual." That includes "a name, social security number, date of birth, and an official driver's license", *United States v. Hurtado*, 508 F.3d 603, 607 n.4 (11th Cir. 2007), as well as Medicare and Medicaid identification numbers. *United States v. Dvorak*, 2009 WL 2905541, *5 (N.D. Iowa 2009) (Medicaid identification numbers); *United States v. Diaz*, 2008 WL 686961, *1 (Medicare HIC numbers).

Put another way, "[t]o establish a violation of §1028A(a)(1), the Government must prove the defendant (1) knowingly transferred, possessed, or used, (2) without lawful authority, (3) a means of identification of another person, (4) during and in relation to a predicate felony offense." *United States v. Abdelshafi*, 592 F.3d 602, 606-607 (4th Cir. 2010).

The enumerated felony crimes are defined in §1028A(c) as including felony violations of 18 U.S.C. §641 (theft of Government property) and of "any provision contained in chapter 63 (relating to mail, bank, and wire fraud)". Chapter 63 includes mail fraud, 18 U.S.C. §1341; wire fraud, 18 U.S.C. §1343; and health care fraud, 18 U.S.C. §1347. *United States v. Silvio*, 2010 WL 77318, *1 (S.D. Ala. 2010) (Section 1028A "includes 'any' offenses in chapter 63 which includes health care fraud").[1]

In order to establish the "without lawful authority" element, the Government is not required to prove that the defendant obtained another person's identification documents by stealing. *United States v. Hurtado*, 508 F.3d 603, 608 (11th Cir. 2007). For example, a health care provider who initially had lawful authority to use Medicare or Medicaid numbers of patients for proper billing purposes would "not have 'lawful authority', however, to use [Medicare or] Medicaid patients' identifying information to submit fraudulent billing claims." *Abdelshafi*, 592 F.3d at 608.

In order to establish the required "knowingly" mental state, the Government must prove that the defendant knew that the means of identification he or she unlawfully transferred, possessed or used did in fact belong to another person. *Flores-Figueroa v. United States*, 129 S.Ct. 1886 (2009).

Sentencing Provisions of Section 1028A

Section 1028A(a)(1) provides that a violator "shall, in addition to the punishment provided for such [enumerated] felony, be sentenced to a term of imprisonment of two years." Under Section 1028(b)(2), "no term of imprisonment imposed on a person under this section shall run concurrently with any other term of imprisonment imposed on the person under any other provision of law, including any term of imprisonment imposed for the felony during which the means of identification was transferred, possessed, or used." Moreover, Section 1028(b)(3) provides that "in determining any term of imprisonment to be imposed for the felony during which the means of identification was transferred, possessed, or used, a court shall not in any way reduce the term to be imposed for such crime so as to compensate for, or otherwise take into account, any separate term of imprisonment imposed or to be imposed for a violation of this section."

The only leniency is contained in Section 1028(b)(4) which gives a sentencing judge the discretion to impose concurrent sentences for multiple aggravated identity theft offenses sentenced by the court at the same time.

Application of Section 1028A to Health Care Fraud Investigations and Prosecutions

In order to be paid by the Medicare and Medicaid programs, as well as by private insurers, health care providers must use their patients' names and identifying information (date of birth, social security number, Medicare number, or Medicaid number). But if health care providers submit false or fraudulent claims to Medicare, Medicaid or private insurers in violation of the mail fraud, wire fraud, or health care fraud statutes, then they are also using their patients' means of identification without lawful authority in violation of Section 1028A.

Implications

Application of the aggravated identity theft statute to health care fraud investigations significantly raises the risks for health care providers because if convicted under Section 1028A they face a minimum of two years imprisonment. More likely, a provider who might be looking at a potential 12-18 month sentence could now be facing a potential 36-42 month sentence after the two year mandatory minimum sentence is added to the underlying fraud sentence.

The result of this increased risk is that providers need to treat any investigation very seriously from the outset and hire skilled defense counsel in order to (1) successfully avoid indictment altogether, (2) negotiate a livable plea agreement which does not include a plea to a Section 1028A violation, or (3) win both the underlying fraud counts and the Section 1028A counts at trial.

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IDENTITY THEFT

from previous page

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Endnote:

[1] *See also United States v. Diaz*, 2008 WL 686961 (S.D. Fla. 2008).

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2010 - 2011 Health Law Section Events

Health Law Section Executive Council Meeting
January 27, 2011
Hyatt Regency Orlando International Airport
3:00 p.m. - 6:00 p.m.

Representing the Physician 2011 CLE
January 28, 2011
Hyatt Regency Orlando International Airport
Course #1157

February 4, 2011 CLE
Join the Health Care Reform Committee (joint committee of the Elder and Health Law Sections of The Florida Bar) in Orlando for this unique Health Care Reform CLE. More information to come soon...

Advanced Health Law Topics and Certification Review 2011
March 5 - 6, 2011
Orlando, Florida
Course #1173

The Florida Bar Annual Meeting
June 22 - 25, 2011
Gaylord Palms Resort, Orlando
Health Law Executive Council Meeting will take place on Thursday, June 23, 2011

HEALTH LAW

from page 1

processes for denied claims, and prohibitions against excluding children based on a pre-existing condition;

- Creation of pilot projects based on the patient-centered medical home concept;
- Incentive payments for the implementation and use of electronic health records;
- Affordable insurance plans through state-run insurance exchanges;
- Extended Medicaid coverage for adults and children; and
- Compulsory insurance mandates requiring individuals to buy health insurance or pay a fine.

Despite congressional passage of these reforms, the issue remains controversial in Florida as the State is seeking judicial repeal of federal laws imposing insurance mandates and extended Medicaid coverage. While the reforms promise increases in coverage, it is argued that the state will be debilitated by the costs.

To help Florida expand its Medicaid coverage, the federal government will likely be providing about $700 million in additional Florida Medicaid funding. Combined with recent Florida budget legislation providing about $270 million to be spent on hospitals, nursing homes, and caner research, efforts to improve Florida's startling healthcare statistics seem hopeful. Additional healthcare funding, of course, paves the way for increases in healthcare fraud. In an effort to combat rampant Medicaid fraud in the South Florida, the federal government has granted the Florida Medicaid Fraud Control Unit ("MFCU") the authority to conduct routine claims review, such as claims screening, billing practice pattern analysis or verification of services rendered. Previously, the Florida Agency for Health Care Administration ("AHCA") was the only state Medicaid agency allowed to use Medicaid matching funds to detect and investigate fraud, and MFCU relied on referrals from AHCA.

Reforms in health insurance coverage, healthcare delivery, and healthcare technology are designed to promote the widespread delivery of efficient healthcare services throughout this state. Naturally, Florida healthcare providers must stay abreast of the changes in provider reimbursement and related incentives designed to promote this goal. Moreover, those who expeditiously implement delivery and technology reforms will reap the greatest benefits.