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How to Effectively
Negotiate a *Certificate of
Compliance Agreement*
with the Office of Inspector General

By Gabriel L. Imperato, Esq., CHC and Vanessa Serrano, Esq.

Due to the submission of false claims or other instances of non-compliance with Federal health care regulations, health care providers and entities sometimes find themselves in a predicament with the Office of Inspector General ("OIG"). In the event of non-compliance, rather than facing the ultimate penalty —

exclusion from Federal health care programs, a health care provider or entity ("Provider") hopes to enter into a corporate integrity agreement ("CIA") or certificate of compliance agreement ("CCA"). When weighing the pros and cons of entering into a CIA versus a CCA, a CCA is often less burdensome and costly than a CIA. Here's why...

Certificate of Compliance Agreement continued on page 2

Florida Legislature Passes
"Anti-Fraud" Bill Affecting
Home Health Agencies,
Nurse Registries, DME
Companies And Medicaid
Providers

By Anne Novick Branan, Esq.
and Barbara Viota-Sawisch, Esq.

Legislation with the potential to make sweeping industry changes in the home health and durable medical equipment industries was recently passed in the Florida Legislature and has been sent to Governor Charlie Crist for signing. The bill, CS/HB 7083, ("Bill") is aimed primarily at cracking down on health care fraud and abuse in these industries. If approved by the Governor, the laws will take effect on July 1, 2008. Addressing other fraud concerns, the Bill mandates additional financial

"Anti-Fraud" Bill continued on page 5

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Corporate Integrity Agreements ("CIA")

A CIA is a written agreement between the OIG and the Provider that requires the Provider to take steps to ensure that it creates and implements a successful compliance program and remains in

compliance with the various Federal health care regulations. While that does not seem like a great deal to ask, the complexity and cost of this process is cumbersome. The OIG must first determine whether a CIA would be an appropriate remedy. According to the open letter published by the OIG on November 20, 2001, the following criteria are considered by the OIG when deciding whether to require a CIA:

- whether the Provider self-disclosed the alleged misconduct;
- the monetary damage to the Federal health care programs;
- whether the case involves successor liability;
- whether the Provider is still participating in the Federal health care programs or in the line of business that gave rise to the fraudulent conduct;
- whether the alleged conduct is capable of repetition;
- the age of the conduct;
- whether the Provider has an effective compliance program and would agree to limited compliance or integrity measures and would annually certify such compliance to the OIG;
- and other circumstances, as appropriate.

Once the OIG decides to implement a CIA as the remedy for the non-compliance, an agreement will then be drafted that will contain several requirements, including auditing, monitoring, and reporting requirements. Most CIAs require a Provider to: 1) hire a compliance officer or appoint a compliance committee; 2) develop written standards and policies; 3) implement a comprehensive employee training program; 4) review claims submitted to Federal health care programs; 5) establish a confidential disclosure program; 6) restrict employment of ineligible persons; 7) hire an Independent Review Organization (IRO) to conduct reviews of the Provider's billing practices policies and procedures; and 8) submit a variety of reports to the OIG. CIAs typically last from three to ten years, with the longer terms on the spectrum assigned for gross misconduct. Under the terms of the CIA, a Provider is typically required to establish a process for reporting misconduct and resolving the issues. A CIA also usually includes stipulated penalties for violating the terms of the agreement.

All of these requirements lead to an increase in costs for Providers. These added costs are due to the additional staff requirements, the additional resources needed to create and implement these internal programs, plus the cost of hiring an IRO. Another major impact on the Provider is supporting the ongoing presence of the IRO and providing the time and resources needed to equip the IRO with the necessary information for the various audits required by the CIA. While these consequences are certainly more favorable than being excluded, they may still impose a significant financial and overall burden to the affected Provider.

Physician Practices May Obtain Higher Payments Under the Government's Electronic Health Record Demonstration Project

By Michael S. Byrnes, Esq.

The U.S. Department of Health & Human Services (DHHS) recently announced a demonstration project that will encourage small to medium-sized physician practices to adopt electronic health records



(EHRs). The demonstration project will provide higher payments to physician practices that meet certain quality measures through the use of EHRs. Up to 1,200 physician practices will be eligible to participate.

The project will begin in the spring and will be conducted by the Centers for Medicare & Medicaid Services over a 5-year period.

Financial incentives will be in the form of a core incentive payment and a bonus. The core payment will be based on a physician practice's compliance with certain clinical quality measures. The annual bonus will be based on the physician practice's score on a standardized survey. The standardized survey will evaluate certain EHR functions that assist in the delivery of care and support the management of patient care.

All participating practices will be required to use an EHR system that can positively affect certain patient care processes, such as clinical documentation and ordering prescriptions. The EHR system must also be certified by a certification body officially recognized by the DHHS, such as the Certification Commission for Healthcare Information Technology.

The overall intention of the demonstration project is to show how the implementation of EHRs will reduce medical errors and improve quality of care for Americans. The demonstration project is part of the DHHS's ongoing effort to become a smart purchaser of health care by "...paying for better, rather than simply paying for more." ■

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Florida Board of Medicine Offers **WARNINGS** for Good Deeds



As tax time fades into distant memory, many providers may be thinking of implementing charitable giving programs for the coming year. Practitioners should be aware, however, that under Florida law, tying charitable giving to patient referrals would constitute a prohibited practice. For example, in a recent decision, the Florida Board of Medicine (“Board”) concluded that the implementation of a charitable-giving program — through which \$10.00 would be donated to the favorite 501(c)(3) charity of an existing patient whenever that patient gave friends or family information regarding the physician’s services — would be an improper inducement to refer others to a physician’s practice in violation of the Florida Medical Practice Act (“MPA”) and the Florida Anti-Kickback Statute (“AKS”).

In May 2007, a Florida-licensed physician petitioned the Board for a declaratory statement concerning whether his proposed marketing program would violate the prohibition against kickbacks in the Florida MPA. The board-certified ophthalmologist performs laser vision correction and other elective procedures. He had engaged a marketing company to devise ways to promote his practice. Among the campaigns it developed, the marketing company proposed a “Patient Charity Program.” In this arrangement, the doctor would donate \$10.00 to an existing patient’s favorite tax-exempt charity whenever the patient gave friends or family information regarding the patient’s laser eye surgery. In addition, if a referred patient received lasik surgery, the doctor would give



another \$10.00 to a charity of the new patient’s choosing.

The Florida MPA prohibits paying or receiving kickbacks or rebates—whether direct or indirect — for the referral of patients. Violation of this provision is grounds for professional discipline. The Florida AKS also prohibits healthcare professionals from paying kickbacks. Under that section, any payment made as an incentive for inducement to refer patients for future services is prohibited and subjects the offender to penalties, including the suspension or revocation of the provider’s license, imposition of administrative fines up to \$10,000 for each offense, or imprisonment of up to 5 years. In this case, the Board found that if the doctor had implemented the “Patient Charity Program,” the doctor would have been “creating an incentive for patients to refer others to Petitioner’s practice. . . .” Moreover, the Board concluded that “such payments [would] constitute prohibited rebates and/or kickbacks” precluded by the Florida MPA and AKS.

Interestingly, the opinion seems to contradict what would normally be considered a kickback in that the payment doesn’t flow to the referral source but to a third party to whom the referral source has no relationship whatsoever. Moreover, in opinions issued as recently as July 2007, the Office of the Inspector General of the Department of Health and Human Services concluded that charitable donations in relationships where the potential for inducement to

provide referrals was present, would not necessarily constitute grounds for the imposition of sanctions under federal law. Here, however, the Florida Board of Medicine surprisingly found that the donations would induce patients to make referrals to the doctor’s practice and would, therefore, be impermissible. Although the Board’s decision is not precedential, it serves as a cautionary note to other physicians about how broadly the Board interprets Florida’s fee-splitting and kickback prohibitions.

It is advisable to consult your health care counsel for further legal aid in deciphering the Board’s rulings. ■

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Certificate of Compliance Agreement ("CCA")

As an alternative, the OIG could choose to impose a CCA. A CCA is typically entered into by Providers who have an effective compliance program in place and who voluntarily disclosed the misconduct or oversight. Additionally, the same factors listed in the OIG's open letter, dated November 20, 2001, are considered when determining if a CCA is appropriate.

Unlike the lengthy CIAs, a CCA usually lasts from three to five years. Another important difference is that an IRO is not required. Instead, the Provider certifies that it will make certain improvements to its already existing compliance program and ensure that there will be no other fraudulent activity. In addition to the agreement, the Provider agrees to report overpayments or events of non-compliance to the OIG, along with annual reports regarding the Provider's compliance activities, during the term of the CCA.

As you might expect, the costs of a CCA are significantly less than a CIA because the Provider is asked to improve its existing compliance program, not create one. Also, the Provider is not required to hire a pricey IRO to complete the audits for it. Instead, the Provider can choose to rely on its own auditing systems or hire an outside auditor. Finally, the typical three-year term of the CCA is shorter than a traditional five-year CIA, so any annual costs for reporting or other requirements also are reduced.

How to Increase the Chances of Getting a CCA Rather than a CIA

The key to getting a CCA from the OIG is to prove to them that the Provider has an effective compliance program in place and that the provider can simply improve the program with the OIG's guidance, rather than having to start from scratch. The following is a list of tips for negotiating a CCA with the OIG:

- **Implement an effective compliance program.** Providers should recognize that the health care industry is heavily regulated and should seek to hire a compliance officer or compliance staff, depending on the nature and size of the practice, to ensure compliance with all of the various regulations. The compliance program should be complete with systems for monitoring billing; recruiting and hiring of employees; handling complaints; educating employees; and handbooks for the staff. Compliance programs could be divided into sections, devoting one section for each of the business aspects, such as billing, human resources and education. All compliance programs should be well documented and easy to access.
- **Compliance program information.** In the event of an investigation, the Provider must supply the OIG with a significant amount of information regarding its

compliance program. The more information provided to the OIG, the better. Examples of information that should be sent to them include but are not limited to:

- compliance policies and procedures;
- compliance training and education requirements;
- details regarding the compliance staff positions and their respective job responsibilities;
- disciplinary standards and punishment to be pursued against employees who violate compliance program standards;
- procedures for handling instances of non-compliance;
- screening methods for hiring all employees;
- physician contracting and recruiting;
- record keeping requirements; and
- billing and reimbursement practices.

The goal is to prove that an effective compliance program exists. Send any and all documents that may demonstrate its presence.

- **Organization.** Providers should make sure that all information sent to the OIG is organized and easy to sort. This is especially important because the Provider will be sending several different types of documents, so binders with tabs and descriptive indexes would be a good idea.
- **Employee awareness.** Demonstrate how the compliance staff informs employees of the various compliance policies and procedures and keeps the employees informed of any important changes in regulations. Different methods that bolster an information program could include an intranet website, compliance meetings or presentations (monthly, annually, etc...), or employee handbooks, to name a few.
- **Cooperation with the OIG.** Make sure that full cooperation is given to the authorities. Answer all requests for information in a professional and timely manner. Provide enough information so that the OIG is satisfied with the level of cooperation.

Overall, demonstrating the existence of a functional and successful compliance program is the main goal. Providers should seek experienced counsel to guide them through the process of establishing effective compliance programs and responding to requests for information from the OIG.



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liability when there is a change of ownership involving any Medicaid provider.

Home Health Agencies and Nurse Registries. The Bill expands the events for which the Agency for Health Care Administration ("AHCA") may impose fines on home health agencies and nurse registries or deny, revoke, or suspend such providers' licenses. Florida-licensed registries or agencies may be penalized for conduct and relationships that have thus far been considered legal under state and Federal law. In fact, many provisions of the Bill are even more restrictive than the Medicare conditions of participation for home health agencies, the Federal Anti-Kickback Statute, or self-referral prohibitions of the Stark Law.

The Bill authorizes AHCA to discipline home health agencies that:

- Have more than one medical director contract in effect at one time, unless a physician-specialist's services are mandated to participate in a Federal or state health care program;
- Prepare or maintain fraudulent patient or home health aide training records;
- Have a pattern of billing any payer for services not provided, or failing to provide services specified in the plan of care for a patient;
- Give remuneration to a referring physician if the agencies do not have a compliant medical director contract in effect;
- Give cash to a Medicaid or Medicare beneficiary.

Both home health agencies and nurse registries may be disciplined if they:

- Give remuneration to a referring physician or to a member of a referring physician's office staff or immediate family;
- Pay for staffing services provided by other agencies or health services pools with which the home health agencies or registries have patient-referral transactions or arrangements;
- Provide services to residents in, or staffing to, an assisted living facility for which the registries or agencies do not receive fair market value remuneration;



- Give payment or other benefit to case managers, discharge planners or staff at a facility from which the agencies or registries receive referrals.

The Bill creates strict, clear prohibitions against the payment and referral relationships listed above. Exceptions that exist in the Federal Anti-Kickback Statute safe harbor regulations, and the Stark Law for certain contractual and employment relationships, and for low value non-cash items, such as logo pens and calendars, do not exist in the Bill. It is yet to be seen how the two very different standards will be interpreted and applied.

Medicaid DME and Medical Supply Providers. State legislators also took aim, though less directly, at the durable medical equipment ("DME") industry by imposing stricter requirements for Medicaid DME and medical supply providers. For dates of service after January 1, 2009, AHCA must limit its network of DME suppliers to organizations that meet certain criteria, including:

- Accreditation by the Centers for Medicare and Medicaid Services approved organizations;
- A physical business location within the State, with a landline business telephone; and
- Strict signage, business hours, and inventory amounts standards.



Medicaid Change of Ownership.

Under the Bill, the seller of a Medicaid provider must provide AHCA with notice, and the buyer must submit a Medicaid provider enrollment application at least 60 days before a change of ownership. If the parties fail to do so, they will be jointly and severally liable for all overpayments and monies, including fines, owed to AHCA. Even if the proper notice is provided, the seller remains liable for all outstanding fines and overpayments owed to AHCA, and the buyer will also be held liable for all outstanding overpayments identified on or before the date of the change of ownership.

Though the potential impact of the Bill on the home health industry and Medicaid providers is evident, the zeal with which AHCA will enforce these requirements is not. Because the Bill is much more restrictive than existing laws, many relationships that are now considered legal may soon be prohibited. The Bill does not contain any provisions granting a grace period, or providing for "grandfathering" of existing arrangements. Therefore, affected health care entities should prepare for the impending consequences of this far-reaching piece of legislation. ■

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KEEPING YOUR *Corporate Compliance Program* IN ACTION

By Vanessa A. Reynolds, Esq.

In a recent continuing education class, a student volunteered that nurses in the hospital-based home health agency for which she worked routinely upcoded home care visits. This was necessary, she explained, to compensate for the low level of reimbursement for the correct code. While she recognized that it probably wasn't proper, she was unaware that she was describing criminal conduct that could expose the nurses and their employer to severe penalties. The student's comment illustrates the importance of targeted and continuing compliance education for all employees in healthcare organizations.

There are seven elements of an effective compliance program, including the implementation of written policies, procedures and standards of conduct to achieve compliance. Of the seven elements, employee education is among the most challenging elements. An effective employee compliance education program should incorporate standardized training for all employees and targeted training of groups for whom non-compliance may pose a greater risk to the organization. In addition, programs should also incorporate compliance methods in their daily operations, as sporadic and subjective efforts lead to situations as described above and could expose healthcare organizations to liability for federal and state sanctions.

Designing a "second wave" of compliance education and training will not only reinforce your organization's commitment to compliance but also empower your employees to support the organization's commitment to ethical practices. Some tactics comprising a "second wave" compliance program may include the following:

1 Develop Relevant Training Modules



Employees should be educated regarding compliance with the Medicare participation requirements relevant to their respective duties and responsibilities and the employee's duty to report misconduct. Get managers and senior executives involved in identifying issues of concern and develop programs to address those issues. Engaged employees will report potential problems before they become avenues of liability.

2 Make Compliance Training a Consistent Practice

Annually distribute principles of conduct, patient care guidelines, and standards for accurate coding and billing. Implement a variety of teaching methods to keep compliance material engaging, including interactive training sessions, bilingual training, and presentations by guest speakers, such as auditors or billing experts. Compliance training should be an ongoing endeavor and when the education is new and relevant, employee awareness will increase.

3 Balance the Message

Compliance training, as per OIG recommendation, should be a condition of continued employment, but employee compliance education should be presented in a positive and constructive manner — not with punitive overtones. Employees won't be engaged by a fear-based program. Training that makes employees aware of the pitfalls of program violations can get them invested in compliance.

4 Survey and Edit

An effective employee education program is a constantly evolving program. Survey employees to gauge their level of compliance understanding prior to and after all training sessions. Invite employees to evaluate the programs and use their suggestions to sharpen the program's focus and target problem areas.

Maintaining corporate compliance program integrity is the goal of any health care organization. An effective compliance program needs educated employees invested in maintaining compliance standards. Such a program calls for regular retraining at all levels of employment. An ongoing education program that makes sense to employees and engages them in the hospital's compliance reinforces the organization's commitment to delivering ethical patient care.

It is advisable to consult a health care attorney or compliance officer to develop a "second wave" corporate compliance program that adheres to state and federal regulations. ■

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CMS Delays the Effective Date of the Expanded Anti-Markup Provisions



By Mike Segal, Esq. and Michele Martello, Esq.



On December 28, 2007, The Centers for Medicare and Medicaid Services ("CMS") delayed the application of the expanded anti-markup rule published in the 2008 Medicare Physician Fee Schedule. CMS has postponed the implementation of the rule until January 1, 2009, instead of the initially scheduled effective date of January 1, 2008.

Generally, CMS invites public comment on a proposed rule, but CMS determined in this case that it would be impracticable and contrary to the public interest to do so. After receiving and reviewing informal comments from various stakeholders, CMS decided to delay the effective date because of the potential disruption of services to patients. CMS intends to use the delay period to clarify the application of new anti-markup

provisions or issue another proposed rule.

The new rule was not delayed, however, with regard to anatomic pathology diagnostic testing services furnished in space used by a physician group practice as a "centralized building" as defined by the in-office ancillary services exception under the Stark regulations.

Currently, the anti-markup rule limits the payment a provider can receive for the technical component of services when the technical component is performed by an outside supplier. Under the new rule, the scope of the anti-markup provisions is broadened to include both the professional and technical components. Specifically, the new provisions will apply to any physician, group practice, independent diagnostic testing facility or other supplier (the "Billing Entity") that wishes to bill for the technical or professional components when the Billing Entity 1) performs the technical or professional components of the diagnostic test at a location outside of the Billing Entity's office as defined by the rule, or

2) orders the technical or professional components to be performed by an outside supplier.

Under the new rule, group practices that rely on the in-office ancillary services exception under Stark will be negatively impacted. The restrictions will essentially deny group practices the ability to utilize the "same building" or "centralized building" option under Stark. Thus, group practices may not be able to continue providing diagnostic testing services due to the inability to profit or recoup overhead costs unless CMS revises the new rule.

Group practices should contact their legal counsel to determine how this new rule will impact their business. ■

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CONTRIBUTING to Education

In *Broad and Cassel's* continuing effort to give back to the community, two of the Firm's Fort Lauderdale office health law attorneys have become involved as board members and faculty for local educational organizations.



Fort Lauderdale Of Counsel Robert Nicholson was recently elected to serve on the Broward Community College Foundation Board of Directors. Nicholson joins more than 35

other board members who support the Foundation's mission to provide advocacy, community awareness, and financial support to Broward Community College

and its students, faculty and staff. A former Assistant United States Attorney, Nicholson has served as a National Health Care Fraud Coordinator, providing guidance to senior Department of Justice officials on health care fraud enforcement, legislation and inter-agency relationships. He has also served as a police officer in Orlando and Tallahassee.

Of Counsel Vanessa Reynolds has been appointed as an adjunct professor for St. Thomas University's School of Business Graduate Health Care Management Program. With two decades of experience in the field of health



law, Reynolds will teach a course titled, "Legal Aspects of Health Care Organizations," as part of a twelve-credit health management specialization program. Reynolds' class, which covers topics such as provider liability, contracts, licensure, compliance, consent and end-of-life issues, will be taught to management level professionals at local health care institutions who are pursuing a Master of Science degree in health care management. Reynolds focuses her legal practice in the areas of medical malpractice and complex litigation, insurance defense, institutional and individual health care provider and multi-hospital public health care system representation. She is a member of several health law organizations, including the American Health Lawyers Association and Florida Hospital Association's Florida Academy of Healthcare Lawyers. ■

Lester J. Perling Awarded Martindale-Hubbell® AV® Rating



Fort Lauderdale Partner Lester J. Perling received an AV® Peer Review Rating from Martindale-Hubbell®, in recognition of his legal skills and professional ethics.

According to Martindale-Hubbell®, an AV® rating is a significant accomplishment — a testament to the fact that a lawyer's peers rank him or her at the highest level of professional excellence — a ranking that is only achieved by five percent of attorneys. Currently, *Broad and Cassel* employs 60 AV® Peer Review Rated attorneys.

A member of the Firm's Health Law and White Collar Civil and Criminal Fraud Defense Practice Groups, Perling is a board-certified health law attorney with extensive experience as a health care executive. He holds a master's degree in Health Care Administration.

A frequent national author and lecturer on various health law and health management topics, he has also taught courses at Florida Atlantic University and Nova Southeastern University, School of Business and Entrepreneurship.

Perling was designated a 2006 and 2007 "Florida Super Lawyer" by *Law & Politics* magazine and was recognized in *Chambers USA* in Healthcare for 2006 and 2007. He was also recognized in 2008 by the legal guide "The Best Lawyers in America," published by Woodward and White. ■

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Joanne Charles Joins *Broad and Cassel*



Broad and Cassel is pleased to announce the addition of Associate Joanne Charles to the Firm's Fort Lauderdale office and Health Law Practice Group.

Charles, formerly a health writer, editor, and researcher, joined the Firm in September 2007. She has experience in developing healthcare fundraising campaigns and drafting physician-written publications. Before joining *Broad and Cassel*, she worked closely with physicians at a medical center to promote hospital services, as well as assist in drafting patient guides and media-related materials.

Charles earned her Bachelor of Arts degree from Syracuse University and received her Juris Doctor from Nova Southeastern University. During her time at the Shepard Broad Law Center, she was an advocate on the Willem C. Vis International Commercial Arbitration Team and was Editor in Chief of the *Nova Law Review*. ■

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