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INSIDE:

Quality of Care:
A Key Area in OIG's Draft Supplemental Compliance Program Guidance for Nursing Facilities

by Myla R. Reizen, Esq.[1], Miami, FL and Dana Bandera, Esq.[2], Miami, FL

The Office of Inspector General ("OIG") actively promotes voluntary compliance efforts within the health care industry by issuing Compliance Program Guidance aimed at the various health care industry sectors. The OIG issued its first Compliance Program Guidance for nursing facilities on March 16, 2000, which essentially covered the basic elements of nursing facility compliance.[3] Most recently, on April 16, 2008, the OIG issued its Draft Supplemental Compliance Program Guidance for Nursing Facilities, for nursing facilities to address changes in the nursing facility industry as well as issues that have gained notoriety since the prior nursing facility Compliance Program Guidance was issued (such as rising public and governmental concern over the quality of care provided in nursing facilities).[4] The Draft Supplemental Compliance Program Guidance, which was designed as a supplement to the first nursing facility Compliance Program Guidance, was open for public comment until June 2, 2008. The OIG is now reviewing those comments and revising the Draft Supplemental Compliance Program Guidance for publication in its final form later this year.

A significant portion of the Draft Supplemental Compliance Program Guidance focuses, in Section III, on risks of fraud and abuse as they relate to quality of care, the submission of accurate

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Message from the Chair

By Jeanne E. Helton, Esq., Jacksonville, FL

The Health Law Section is actively engaged in a number of activities. We continue to expand our membership and are excited to welcome new individuals with fresh ideas and the spirit and drive to implement them.

One of the Section's primary functions is to provide continuing legal education opportunities to our members. The programs we sponsor and support cost more than the fees charged to attend them. However, enhancing the competence and skills of practicing health lawyers is worth the time and investment. Charmaine Chiu, Esq., is Chair of the Section's Continuing Legal Education Committee. She does an outstanding job of putting together programs with timely and relevant topics, with the assistance of some of our section members that are generous with their time. This year, we offered a couple of teleconferences to see whether they would be well received. They were very successful and so we plan to offer more in the coming months. On January 16th, in connection with The Florida Bar's Midyear meeting in Miami, we will be hosting a CLE called Representing the Physician. Lester Perling, Esq. and Alan Gassman, Esq.

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MESSAGE FROM THE CHAIR

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are taking responsibility for setting this up so you don't want to miss it. Sandra Greenblatt and James "Chet" Barclay are chairing the 2009 Advanced Health Law Topics and Certification Review Course, scheduled for March 6-7, 2009 in Orlando. This is an outstanding program that is very useful for those pursuing certification (the deadline for registering for the 2009 exam has passed but consider it for 2010!) and others that just want to get an intensive two day review of the significant health care laws. We are now putting together our CLE to be held in June, in Orlando, in connection with The Florida Bar's Annual Meeting. Finally, James "Chet" Barclay and Lisa Barclay are putting together a Fundamentals of Florida Health Law program, tentatively scheduled for September, 2009 in Tampa. This is a new undertaking by our Section, designed to serve as an introductory program for individuals that are just wading into the health care waters for the first time, and others that may have been out of the water for a bit and want to brush some rust off before starting anew. In either case, this is a program to calendar and look for future announcements!

One of our section members, Bernabé A. Icaza, Esq. has agreed to continue as our Health Care Section Newsletter Editor. He does a great job of putting together information in a succicint format that is readable and relays valuable information. James Chet Barclay, Esq. continues to serve as our "webmaster" with regard to our Section website, www.flabarhls.org. This is a good site to bookmark and check periodically. We try to post notices and meeting schedules, minutes and other information that you may find useful. If you have information about any new development in Health Law, please consider sending it to Chet Barclay to post on the website for informational purposes.

In addition to the CLE schedule and informational communications described above, our Section is undertaking a review and possible amendment of our Section bylaws. It's been quite a few years since we updated them and so its time to bring them into this century. Additionally, in furtherance of our desire, as a Section, to truly add value and be of benefit to you, we are preparing a survey of our members to find out how we can better enhance your professional practice. We hope to get it out to our members in the Spring and look forward to receiving your feedback. When you receive it, please take a few moments to complete it. Lew Fishman, Esq. is to be commended for volunteering to Chair the Bylaws Committee and prepare an initial draft of the Section Survey.

Our Section's Public Health Law Committee is now meeting on a regular basis via telephone conference calls and is Co-Chaired by Rodney Johnson, Esq. and Walter Carfora, Esq. We will be posting meeting information on our website so those interested in joining this Committee or simply participating in their discussions can do so. You also can contact Rodney or Walter directly for further information. Public Health issues touch just about every area of health law and so many of you would benefit from becoming involved.

John Buchanan and I have been working this year, along with about 20 outstanding health law practitioners in Florida, preparing for the publication of the 2009 Health Law Handbook. This book will be updated from the 2007 version and includes some additional new chapters on topics as diverse as the Schiavo litigation and Restrictive Covenants under Florida law. This was a popular seller during 2007 and 2008 for two reasons: it is inexpensive and quickly becomes an armchair desk reference chocked full of useful information. We hope to have the 2009 Handbook available in January, 2009.

Finally, I want to take a moment to encourage each of you that have an interest in health law to consider becoming more active in our Section. Everyone is welcome to attend our Executive Council meetings and most of the Committees would welcome additional participation. Participation in Section activities offers you an opportunity to meet and make friends with colleagues from around the state that work to stay at the top of their game. Whether you practice as a solo practitioner, in a mid-size or large firm, as an in-house counsel or with a government agency, you can benefit the Section and yourself by becoming involved. If you have a particular expertise in a specific area and would be interested in presenting at one of our programs, live or via teleconference, please contact Charmaine Chiu, Esq.

Finally, a special thank you to Troy Kishbaugh, Esq., Lester Perling, Esq., Cynthia Mikos, Esq. (Chair-Elect, Treasurer and Secretary, respectively,) and Valarie Yarbrough, our designated Bar Reprehensive for all their hard work on behalf of the Section. Their personal contributions significantly enhance our Section and certainly make my job much easier!

Please consider joining us at the Midyear Meeting of The Florida Bar. The Health Law Executive Council is meeting the afternoon of January 15th at the Hyatt Regency at the Miami Convention Center. Our "Representing the Physician " CLE is set for January 16th. Kick off 2009 by taking the initiative to become active! See you there!

Editor's Note

by Bernabe A. Icaza, Esq., Ft.Lauderdale, FL

Welcome to the latest issue of the Florida Bar Health Law Section e-newsletter. This edition contains six articles on a number of interesting topics. We are grateful to the authors who submitted these articles for publication.

I would like to briefly bring to your attention a number of important new developments during the past few months. On August 19, 2008, CMS published the final 2009 inpatient PPS rule containing several important revisions to Stark. Most notably, this rule contains important revisions to the physician "stand in the shoes" provisions, the "set in advance" requirement, and restricts "under-arrangements", per click space and equipment lease arrangements, and percentage-based compensation arrangements. With the exception for under arrangements and per click and percentage-based compensation arrangements which are effective October 1, 2009, the changes are effective October 1, 2008.

During the past few months the OIG has issued a number of OIG Advisory Opinions. Most notably, the OIG said it would not recommend the imposition of administrative sanctions on a health system that proposed to give $10 gift cards to patients that were dissatisfied with their service even though it held that the proposal could constitute prohibited remuneration under the Anti-Kickback Statute.

The OIG concluded that it could impose administrative sanctions on a proposal for a group practice to provide space, equipment and personnel to other physician practice groups through block leases. Notably, the OIG said that while the proposed arrangement could satisfy the applicable safe harbors for space and equipment rental and personal services the result of the proposal was such that it could implicate the AKS and be prohibited since it allowed the group the opportunity to generate a fee outside of the financial stream protected by the safe harbor.

Also, in Florida there were a number of interesting developments during the past few months. Most notably was a recent decision from the First District Court of Appeals holding that the Agency for Health Care Administration (AHCA) statistical formula for cluster sampling used by AHCA to calculate Medicaid overpayments is not an unpromulgated rule. Also, during the summer a complaint for injunctive and declaratory relief was filed in U.S. District Court in Tallahassee seeking to bar enforcement of Amendment 7 as violative of the U.S. Constitution. The complaint was filed by the Florida Hospital and Medical Associations and a number of hospitals throughout the state.

In South Florida the Office of the U.S. Attorney was once again busy prosecuting health care fraud cases. During the 2008 fiscal year ending September 30, 2008, the number of Defendants charged with health care fraud increased to 245 from 111 in 2006 according to the Office of the U.S. Attorney. This amounted to approximately $800 million in alleged fraud cases an increase from $138 million in 2006.

As the end of the year nears, it is time to start planning for CLE programs scheduled during the Spring of 2009. The ABA Health Law Section's Emerging Issues meeting is scheduled for February 2009 in Orlando, Florida. For additional information please contact Shannon Hartsfield at Shannon.Hartsfield@hklaw.com. Also, please mark your calendars for the 2009 Advanced Health Law Topics and Certification Review CLE course that is scheduled for March 6-7, 2009, also held in Orlando Florida.

Once again, we are grateful to all the authors who submitted articles for publication and for the assistance rendered by the Florida Bar. For those of you wanting to submit articles for publication for our next edition please forward them to my attention at IcazaHealthLaw@hotmail.com.

QUALITY

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claims, the Federal anti-kickback statute, and "other" risk areas. First, this section notes that compliance with applicable quality of care standards and regulations is essential for the lawful behavior of nursing facilities. In the case of a "failure of care on a systemic and widespread basis" of a nursing facility, such failure can result in the nursing facility's liability for submitting false claims for reimbursement to the Government under the Federal False Claims Act and the Civil Monetary Penalties Law. In this respect, the OIG highlights the risk areas of sufficient staffing, comprehensive resident care plans, appropriate use of psychotropic medications, medication management, and resident safety.

The OIG points out the critical nature of staffing numbers and staff competency and reminds nursing facilities that federal law requires sufficient staffing necessary to "attain or maintain the highest practicable physical, mental and psychological well-being of residents." Because the needs of a particular facility may be constantly changing, nursing facilities are encouraged to regularly reassess such needs to ensure competent levels of care. Items to be taken into consideration when assessing staffing models include, among others, staff skill levels, staff-to-resident ratios, staff turnover, staffing schedules, disciplinary records, adverse event reports, and interviews with residents and residents' families.

The Draft Supplemental Compliance Program Guidance indicates that Medicare and Medicaid require nursing facilities participating in these programs to develop a comprehensive care plan for each individual resident, addressing the resident's medical, nursing, and mental and psychosocial needs, including reasonable objectives and time tables. Such plans should be designed to ensure that residents receive coordinated, multidisciplinary care and, therefore, require the participation of a full multidisciplinary team. As such, nursing facilities should take steps to ensure coordination and cooperation in the development and execution of each resident's comprehensive care plan. Meetings between caregivers should be appropriately scheduled and documented and may also involve the resident or the resident's family members. The nursing facility should also take steps to seek to ensure that the resident's attending physician is involved in such planning and conducts regular visits with and evaluations of the resident.

The appropriate use of psychotropic medications and medication management are also important risk areas to be addressed. The OIG notes that, in its enforcement and compliance monitoring activities, it has noticed the inappropriate use of psychotropic medications, such as chemical restraints and unnecessary drug usage. In light of federal law requirements, nursing facilities must ensure that there is an adequate indication for use of psychotropic medications and must also carefully monitor, document and review use by each resident. Care providers should be educated on how to monitor, document and review such use. Proper medication management requires the appropriate training of staff involved in the nursing facility's pharmaceutical care and measures to ensure compliance with the Centers for Medicare and Medicaid Services requirements and address the potential conflicts of interest that consultant pharmacists may experience.

The final issue addressed by the "quality of care" section of the Draft Supplemental Compliance Program Guidance is resident safety, which is discussed in terms of promoting resident safety, resident interactions, and staff screening. Nursing facilities must comply with Federal regulations mandating development and implementation of policies and procedures to prohibit mistreatment, neglect, and abuse of residents. Such compliance programs should include policies, procedures and practices to prevent, investigate and respond to instances of potential resident abuse. Confidential reporting is key to the success of such programs and the OIG recommends the establishment of a dedicated hotline for reporting violations and the protection of employees from retaliation. Care should also be taken to prevent resident on resident abuse by monitoring residents at risk for aggressive behavior. Finally, staff screening should include verification of education, licensing certifications, and training as well as a comprehensive examination of a prospective employee's criminal record in all states in which the person has worked or lived.

The article is only meant to provide general highlights of the Draft Supplemental Compliance Program Guidance. For a complete review of the Draft Supplemental Compliance Program Guidance, one should refer to the OIG website at www.oig.hhs.gov.

Endnotes:

1. **Myla R. Reizen, Esq.**, is an attorney with the Law Firm of Jones, Walker, Waechter, Poitevent, Carrère & Denègre, L.L.P. She has extensive experience with healthcare compliance and investigations. Ms. Myla has represented numerous types of healthcare providers, such as hospitals, nursing facilities, and home health agencies. She can be reached at (305) 679-5716 (Email: mreizen@joneswalker.com).
2. **Dana Bandera, Esq.**, is an attorney with the Law Firm of Jones, Walker, Waechter, Poitevent, Carrère & Denègre, L.L.P., who assists with healthcare regulatory and transactional matters (Email: dbandera@joneswalker.com).
3. The OIG issued a Compliance Program Guidance for Nursing Facilities on March 16, 2000 (*See* 65 FR 14289 March 16, 2000).
4. The OIG issued a Draft Supplemental Compliance Program Guidance for Nursing Facilities on April 16, 2008 (See 73 FR 20680).

This newsletter is prepared and published by the Health Law Section of The Florida Bar.

AHCA Interprets Clinical Laboratory Kickback Prohibitions for the First Time

by Lester J. Perling, Esq.[1], Ft. Lauderdale, FL

The Agency for Health Care Administration ("AHCA") recently issued a pair of Declaratory Statements involving the propriety of certain practices pursuant to the kickback prohibitions in Florida's clinical laboratory law. Specifically, the declaratory statements address the ability of clinical laboratories to enter into discount arrangements with skilled nursing facilities ("SNF"), and the provision of on-site laboratory supplies and collection personnel in physicians' offices. The arrangements discussed in both declaratory statements, according to AHCA, would violate the kickback provisions in the Florida's clinical laboratory law and SNF laws, as well as regulations specific to clinical laboratories.

The precise question presented to AHCA in *In Re: Petition for Declaratory Statement of American Health Associates Clinical Laboratory, Inc.* [2] ("AHA Statement") was whether Florida's clinical laboratory laws permitted a laboratory to discount its charges to a SNF for services provided to the SNF's patients for which payment is made under Medicare Part A if (a) the laboratory's discounted charges are below its actual costs for providing the services, and (b) the laboratory also receives referrals from the SNF for the provision of undiscounted laboratory services to the SNFs' patients under Medicare Part B. In a decision that went well beyond the question presented, AHCA seemed to declare that a laboratory's reduction of fees charged to a SNF for ancillary laboratory services for Medicare Part A patients would be prohibited under section 483.245(1), Fla. Stat.,[3] governing clinical laboratories.

Although not asked to do so, AHCA also addressed the laws governing SNFs. According to AHCA, Section 400.17, Fla. Stat.[4], which applies to SNFs, prohibits a clinical laboratory from offering discounts to SNFs "when the discount is offered with the intent to influence... the referral by the SNF of Medicare Part B patients to the laboratory." Thus, according to AHCA, laboratories that participate in the arrangement could be found to be violating the laws governing both clinical laboratories and SNFs. AHCA did not make any declaration regarding the participation of SNFs in the discount arrangements.

Notwithstanding its overbreadth, the AHA Statement is consistent with the long-standing opinion of the Department of Health and Human Services' Office of the Inspector General ("OIG") regarding arrangements that "swap" Medicare Part A discounts for referrals of Part B business. "Swapping" occurs when a provider discounts its services to a referral source, such as a SNF, as an inducement for the SNF to refer other, non-discounted business to the provider. As early as 1994, the OIG issued a Special Fraud Alert[5] relating to arrangements for clinical laboratory services, in which it stated that "when a laboratory offers or gives to a referral source anything of value for less than fair market value, an inference may be made that the thing of value is offered to induce the referral of business" in violation of the Federal Anti-Kickback Statute.[6] Thereafter, in 1999, in three Advisory Opinions,[7] the OIG addressed arrangements similar to those described in the AHA Statement and concluded that the proposed arrangements could constitute prohibited "swapping" under the anti-kickback statute.

Arguably, the AHA Statement interprets Florida laws prohibiting kickbacks in a broader manner than the OIG's interpretation of the federal anti-kickback statute: AHCA appears to say that clinical laboratories absolutely cannot discount their services that are payable by a SNF under Medicare Part A with the intention of obtaining referrals from the SNF for business that the laboratory can bill directly to Medicare Part B.

AHA has appealed the AHA Statement to the First District Court of Appeal. That appeal has been stayed in anticipation of a petition for a modified declaratory statement to correct a perceived error made in the AHA Statement with regard to the seemingly broad prohibition against all discounts by clinical laboratories to SNFs.

In *In Re: Petition for Declaratory Statement of Dominion Diagnostics, LLC*[8] ("Dominion Statement"), AHCA was asked to determine: (1) whether a clinical laboratory may provide physicians with free specimen cups that, in addition to serving as collection devices, also have the ability to provide on-site laboratory test results;[9] and (2) whether a clinical laboratory may provide free personnel at a physician's office to collect and ship specimens to the laboratory's facility. AHCA addressed each of these questions in turn.

Regarding the provision of free specimen cups, AHCA asserted that, although the petition indicated that the clinical laboratory would provide the specimen cups for free, it did not indicate whether it would do so in order to induce the physicians to refer their patients to its laboratory. Consequently, AHCA did not declare with certainty whether the arrangement would violate Section 458.245(1), Fla. Stat., but did remind the Petitioner that the United States Department of Health and Human Services has explained that "when a laboratory gives an item or service for free to a referral source, an inference may arise that the item is offered to induce the referral of business."

AHCA went on to declare that the proposed arrangement was nevertheless improper because it would violate Rule 59A-7.020(15), Florida Administrative Code, which allows laboratories to provide specimen cups to physicians for free *only* for the collection, transportation, processing, or storing of specimens.[10] Because the proposed arrangement would provide physicians with specimen cups that also, at least

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arguably, perform actual laboratory tests, the Agency concluded that the proposed arrangement would subject the laboratory to licensure sanctions for violating Rule 59A-7.020, Florida Administrative Code.

With respect to the provision of personnel to process and ship the specimens, AHCA noted that it is aware that a Special Fraud Alert issued by the OIG expressly permits clinical laboratories to provide personnel to physicians' offices to collect specimens in certain situations.[11] However, it made clear that the Special Fraud Alert addressed only the applicability of federal laws. Under Florida law, AHCA concluded that providing personnel or assistance of any kind to perform any duties regarding processing specimens is expressly prohibited under Rule 59A-7.020(15), Florida Administrative Code.[12]

These two declaratory statements are important because they reflect a clear distinction between what is permissible under current interpretation of federal law versus what is permissible under AHCA's interpretation of Florida law. Clearly, Florida law is more restrictive in this area than federal law, which suggests that efforts should be made by both AHCA and the private sector to bring some consistency between state and federal law in this area.

(Endnotes)

1. Lester J. Perling, Esq., is an attorney with the Law Firm of Broad and Cassel. Mr. Perling is Board Certified in Health Law by The Florida Bar. He is a partner with Broad and Cassel, practicing in its Fort Lauderdale office. The author wishes to thank Barbara Viota-Sawisch, Esq. for her assistance in preparation of this article. Mr. Perling can be reached at 954-764-7000 (Email: lperling@broadandcassel.com).

2. FRAES No. 2008004635 (2008).

3. Section 483.245(1), Fla. Stat., provides that it is unlawful for any person to pay or receive any kickback or rebate in any form whatsoever to or from any organization or person, either directly or indirectly, for patients referred to a clinical laboratory.

4. Section 400.17(2), Fla. Stat., prohibits anyone who furnishes items or services to a nursing home resident from offering or receiving any kickback in connection with the provision of the items or services. A kickback is defined as payment for items or services that is returned to the payor (e.g., SNF) by the provider (e,g., laboratory) for the purpose of inducing the SNF to purchase items or services from the laboratory.

5. Special Fraud Alert, Arrangements for the Provision of Clinical Lab Services, 59 Fed. Reg. 65372 (Dec. 19, 1994).

6. The anti-kickback statute prohibits knowingly and willfully offering, paying, soliciting or receiving any remuneration to induce referrals of items or services reimbursable by federal health care programs. See 42 USC § 1320a-7b.

7. OIG Advisory Opinion Nos. 99-2, 99-3, 99-13 (1999).

8. FRAES No. 2008008228 (2008).

9. According to the Petition, the on-site tests that the specimen cups can render are categorized as either waived tests or moderately complex tests under federal law. The Petition also indicated that the approximate cost of each cup was $6.00 to $8.00.

10. Rule 59A-7.020(15), Florida Administrative Code, prohibits the provision of computer and office supplies, except for items or supplies that are for the sole purpose of (1) collecting, processing, storing, and transporting specimens to the laboratory; (2) transmitting laboratory information to the laboratory; or (3) ordering and communicating laboratory test results and other information between the physician and the laboratory. It also prohibits laboratories from providing free "test kits" to physicians.

11. Special Fraud Alert, Arrangements for the Provision of Clinical Lab Services, 59 Fed. Reg. 65372 (Dec. 19, 1994).

12. Rule 59A-7.020(15), Florida Administrative Code, prohibits the "provision of personnel or assistance of any kind to perform any duties for the collection or processing of specimens."

New Law Means Increased Protection of Employee and Insurance Beneficiary Information

by Ronald A. Christaldi, Esq., and Amy Rani Nath, Esq.*

The recent enactment of the Genetic Information Nondiscrimination Act of 2008, or GINA, indicates a move at the federal level to protect employees and health insurance beneficiaries who once feared discrimination on the basis of their genetic defects. GINA prohibits discrimination by employers and health insurers on the basis of genetic information, and its enactment has been years in the making. The bill passed by a unanimous 95-0 vote in the United States Senate on April 24th, and subsequently passed by a nearly-unanimous 414-1 vote in the United States House of Representatives on May 1st. President Bush officially signed the bill into law on May 21st.

GINA's purpose is to establish a national and uniform basic standard to protect the public from genetic discrimination, thereby encouraging individuals to take advantage of genetic testing, technologies, research, and new therapies. It is divided into three parts: Genetic Nondiscrimination in Health Insurance, Prohibiting Employment Discrimination on the Basis of Genetic Information, and Miscellaneous Provisions. The health insurance measures will go into effect in May, 2009, and the employment measures will be effective in November, 2009.

The first part covers amendments to ERISA, the Public Health Service Act, the Internal Revenue Code, and the Social Security Act. It also adds to the Social Security Act a section which applies HIPAA regulations to genetic information in that it requires genetic information be treated as health information under the HIPAA privacy regulation. Thus, group health plans, insurers, and issuers of Medicare supplemental policies must treat genetic information as an individual's protected health information.

Ultimately, GINA may aid in medical treatment as healthy individuals may be more likely to get tested for their genetic predisposition to certain diseases and disorders without the fear of employment discrimination or increased insurance premiums. Additionally, increased genetic testing may promote medical advances, as researchers may be more likely to develop treatments for diseases with hereditary links. In light of the recent enactment of GINA, the legal profession should remain alert to the seemingly ever-changing area of health law.

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Physicians as DME Suppliers Under Stark

by Harold E. Kaplan, Esq.[1], Coral Springs, FL

Physician practices have discovered, or so they believe, that they can obtain Medicare DME supplier numbers and then provide their Medicare patients with various items of durable medical equipment ("DME") and bill for and collect for these DME supplies. Will they be in full compliance with the law if compliance requires the physician's personal rendition of supplier services?

As this article notes, with strict compliance of the Stark Law, codified at 42 U.S.C. §1395nn and its enabling regulations codified at 42 C.F.R. part 411, subpart J, and particularly 42 C.F.R. 411.355 (the "Regulation"), DME products could be legally supplied to Medicare patients by physicians and medical practices, provided that they become Medicare DME suppliers. However, the question remains, is there actual compliance by physicians and their practices of the prescriptive requirements in the Stark Law and the Regulation and especially the personally performed standard?

We know that the Regulation permits a certain limited number of DME under the in-office ancillary services exception, and provides in pertinent part as follows:

(4) For purposes of paragraph (b) of this section [in-office ancillary service exception], DME covered by the in-office ancillary services exception means canes, crutches, walkers and folding manual wheelchairs, and blood glucose monitors, that meet the following conditions:

(i) The item is one that a patient requires for the purpose of ambulating, a patient uses in order to depart from the physician's office, or is a blood glucose monitor (including one starter set of test strips and lancets, consisting of no more than 100 of each). A blood glucose monitor may be furnished only by a physician or employee of a physician or group practice that also furnishes outpatient diabetes self-management training to the patient.

(**ii**) The item is furnished in a building that meets the "same building" requirements in the in-office ancillary services exception as part of the treatment for the specific condition for which the patient-physician encounter occurred.

(**iii**) The item is furnished personally by the physician, who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice.

(iv) A physician or group practice that furnishes the DME meets all DME supplier standards set forth in Sec. 424.57(c) of this chapter.

(v) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(vi) All other requirements of the in-office ancillary services exception in paragraph (b) [in-office ancillary services] of this section are met."

Pay particular attention to key provisions in the Regulation. It applies only to canes, crutches, walkers and folding manual wheelchairs and blood glucose monitors (as further amplified within the Regulation). The item must be personally furnished by the physician, who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice and the physician or the group practice must meet all of the supplier standards. For reference to the supplier standards, see T*he Florida Bar Health Law Section Newsletter* article, DMEPOS Suppliers Must Comply with the Twenty-One Supplier Standards (September, 2006).

The author has learned that numerous medical practices are also dispensing DME items not listed in the Regulation, presumably relying on the Stark exception which permits physicians to personally render services. However, is the personal service exception being complied with? This question is also in the minds of Centers for Medicare and Medicaid Services ("CMS") officials and was confirmed by a high level CMS representative who the author recently spoke with.

Nevertheless, many medical and surgical practices have obtained supplier numbers and are dispensing various DME items. Whether or not these practices are in compliance with Stark is an open question.

Importantly, CMS addressed the issue of physicians becoming DME suppliers in its written comments which appeared in the Federal Register when it published the Phase III rule. See 72 Fed. Reg. 51,012 (Sept. 5, 2007). A portion of those comments are reproduced below and directly address the issue of physicians as DME suppliers. CMS' comments are highly instructive for the health law practitioner who must advise clients in this complicated area of law. They also assist the health law practitioner formulate appropriate correspondence to clients, in order to assure that there is no misunderstanding about what must be done to comply with the law.

CMS' comments which begin on page 51,019 of the Federal Register, state in pertinent part as follows:

"We note that the furnishing of durable medical equipment (DME) and supplies by a referring physician requires a different analysis than the mere refilling of an implantable pump. There are few, if any, situations in which a referring physician would personally furnish DME and supplies to a patient, because doing so would require that the physician himself or herself be enrolled in Medicare as a DME supplier and personally perform all of the duties of a supplier as set forth in the supplier standards in Sec. 424.57(c).

DME suppliers are entities that provide services under the specific Part B benefit for the provision of medical equipment and supplies for use in the patient's home. These entities must be enrolled with the appropriate Medicare contractor as a DME supplier and must meet all of the professional supplier standards and quality standards that we require through regulations and administrative or program instructions. The enrollment requirements and professional supplier standards are not waived in those situations in which a physician furnishes DME directly to the patient. The services to be personally performed by the physician would include, but not be limited to, the following, as appropriate--

Personally fit the item for the beneficiary;

Provide necessary information and instructions concerning use of the DME;

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Advise the beneficiary that he or she may either rent or purchase inexpensive or routinely purchased DME;

Explain the purchase option for capped rental DME;

Explain all warranties;

(Usually) deliver the DME to the beneficiary at home; and

Explain to the beneficiary at the time of delivery how to contact the physician in his or her capacity as a DME supplier by telephone.

A referring physician claiming to provide DME personally would need to maintain adequate documentation to establish that the physician personally performed these and other required DME supplier activities.

All of these supplier requirements would need to be satisfied in order for a physician to be considered to be providing personally DME items and supplies. This is true for all DME furnished by a physician, including, for example, continuous positive airway pressure (CPAP) equipment.

We believe that it is highly unlikely that a referring physician would meet the criteria for personally performed services when dispensing CPAP or other DME equipment. Thus, the dispensing of CPAP equipment by a physician would almost always constitute a "referral" for purposes of the physician self-referral statute, as would the dispensing of CPAP equipment by anyone else affiliated with the referring physician, such as a nurse or physician assistant. We note that CPAP equipment is DME that does not qualify for the in-office ancillary services exception." (Underline supplied)

In summary, medical practice's may apply for and become Medicare DME suppliers. However, health lawyers must remember that Stark and the Regulation requires that the personal service exception be fully complied with. What's on the ground may be quite different.

(Endnotes)

1. Harold E. Kaplan, Esq. is a Board Certified Health Law Attorney, Former Chair of and currently a member of the Executive Council of the Health Law Section. His office is in Coral Springs, Florida where he principally represents physicians and other health care providers for a broad range of matters.

Department of Health Enforces Financial Responsibility Requirements-Finally

by Marshall Burack, Esq.[1],Miami, FL; Joseph W. Rugg, Esq.[2], Tampa, FL; Stephen Prom, Esq.[3], Jacksonville, FL; Randal Fairbanks, Esq.[4], Jacksonville, FL

The Florida Department of Health recently took unprecedented action to enforce the Financial Responsibility provisions of the Florida Medical Practice Act by suspending the medical license of a physician who failed to pay an unsatisfied malpractice judgment.

With the increasing cost of malpractice insurance, a growing number of physicians in Florida have elected to "go bare" and not maintain professional liability ("malpractice") insurance. The Florida Statutes provide patients with financial protection against damages caused by professional malpractice by requiring that physicians satisfy certain financial responsibility requirements as a condition of maintaining an active medical license. A physician can satisfy the financial responsibility requirements (set forth in Section 458.320, Fla. Stat.) by: i) obtaining and maintaining professional liability insurance in the minimum amounts specified in the statute ($250,000 per claim, $750,000 annual aggregate for physicians who have hospital staff privileges or who perform surgery at a licensed ambulatory surgical center), ii) establishing and maintaining an escrow account in the specified minimum per claim amount; or iii) obtaining and maintaining an irrevocable letter of credit in the specified minimum amounts.

Alternatively, a physician who does not maintain the requisite insurance, escrow account, or letter of credit may still comply with the statutory requirements if, upon the entry of an adverse final judgment from a medical malpractice claim, the physician pays the judgment creditor, within 60 days after the judgment becomes final, the lesser of the amount of the judgment or $250,000. See Section 458.320(5)(g)1, Fla. Stat. The statute expressly provides that the Department of Health shall issue an emergency order suspending the license of any physician who fails to satisfy a medical malpractice judgment (or otherwise furnishes the Department a notice of appeal, an order staying execution of the judgment, or copy of a supersedeas bond) within 30 days of receiving a notice from the Department.

The threat of losing one's medical license for failure to satisfy a malpractice judgment has, until recently, been a hollow threat. The Department of Health has rarely, if ever, taken action to suspend a physician's license because the physician failed to satisfy a malpractice judgment or did not otherwise comply with the statutory financial responsibility requirements. Many physicians who have had large malpractice judgments entered against them have avoided such judgments, through personal bankruptcy or other means, and have continued practicing medicine.

A recently issued Order of Emergency Suspension of License of Manual A. Martinez, M.D. may indicate the Department of Health is finally prepared to enforce the financial responsibility requirements. In August, 2007, a judgment in the amount of $2,572,833.21 was entered against Dr. Martinez. In October, 2007, the plaintiff's attorney notified the Department of Health that Dr. Martinez had failed and/or refused to make any payment on the judgment. In December, 2007, the Department delivered to Dr. Martinez a notice of failure to satisfy the judgment, advising him that his license would be suspended if he did not provide the Department with documentation showing satisfaction of the judgment in the statutory amount of $250,000, or a notice of appeal, court order staying execution, or a copy of a supersedeas bond. None of such items were provided to the Department, so the Department, acting pursuant to the requirements of Section 458.320(5)(g)2 of the Florida Statutes, issued an Emergency Order on March 20, 2008, suspending Dr. Martinez's license to practice medicine.

There is no indication on the face of the Order as to why the Board acted to suspend Dr. Martinez's license while other physicians who failed to pay judgments did not suffer the same consequence. It may be significant, however, that Dr. Martinez had been the subject of an Administrative Complaint filed by the Department of Health in May, 2005 alleging he had prescribed excessive narcotics in violation of the Medical Practice Act. The Complaint resulted in a Consent Agreement and an administrative fine. Query as to whether the Department would have moved to suspend Dr. Martinez's license for failure to satisfy a judgment if his record had otherwise been clean?

In any event, the lesson to be learned from this case is that, if you have had a malpractice award entered against you and you receive a notice from the Department of Health to pay the judgment, your license to practice medicine is at risk if you do not satisfy the judgment, up to the statutory amount.

(Endnotes)

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CMS 2009 Proposed Physician Fee Schedule—Further Restrictions on Physicians' Imaging Operations

by Marshall R. Burack, Esq.[1], Miami, FL

The Centers for Medicare and Medicaid Services (CMS) is determined to restrict the ability of physician groups to provide diagnostic imaging services for their Medicare patients.

On July 7, 2008 CMS published its 2009 Proposed Medicare Physician Fee Schedule Rule (PFS). The PFS contains several proposed Stark Law regulations, including two that take dead aim at the provision of diagnostic imaging services by physicians pursuant to the Stark Law exception for "in-office ancillary services."

Required Enrollment as IDTF

The proposed rule would require all physicians and non-physician practitioner organizations which provide diagnostic testing services for Medicare beneficiaries to enroll with the Medicare program as an independent diagnostic testing facility (IDTF). Requiring physician groups which provide imaging services for Medicare patients to enroll as IDTFs would subject such groups to the heightened IDTF performance standards adopted by CMS in 2007. The IDTF performance standards were established to improve the quality of diagnostic testing services furnished to Medicare beneficiaries. Heretofore, physician groups that provide imaging services have been able to enroll as a physician office or clinic and have not been subject to these IDTF performance standards. In fact, in recent months, a number of imaging facilities in Florida which had been enrolled as IDTFs terminated such enrollment and obtained a Medicare number as a physician group or non-physician practitioner organization, so as to be able to avoid the new IDTF performance standards.

CMS is seeking to "level the playing field" by applying the stricter IDTF performance standards consistently for all imaging centers, regardless of who owns the center. Among other provisions, the IDTF performance standards prohibit the sharing or part-time leasing of diagnostic testing facilities. Subjecting physician groups to this requirement would prohibit physician groups from entering into block leases or shared use agreements for imaging facilities and equipment, effectively preventing physician groups from providing imaging services for Medicare patients on a part-time basis. After the proposed rule becomes effective, only practices which are large enough to support their own imaging facility on a full-time basis will be able to own and operate an imaging facility. CMS has proposed that the rule become effective for existing providers of imaging services as of September 30, 2009. For newly enrolling suppliers, the effective date of the rule would be January 1, 2009.

Anti-Markup Rule

A second assault on physician imaging activities is contained in the section of the PFS dealing with Anti-Markup issues. In November, 2007, CMS proposed a broad expansion of the existing anti-markup rule by proposing that the prohibition against "marking up" the cost of a diagnostic test would apply when such test is not performed "in the office" of the billing physician or other supplier. This proposal would have significantly narrowed the exception, set forth in the Stark Law, which permits a physician group to provide in-office ancillary services in the "same building" in which it provides other physician services, or, under certain circumstances, in a "centralized building" used by the physician group for the provision of ancillary services.

In response to numerous comments objecting to the uncertainty as to what was meant by "in the office of the billing physician or other supplier," and the potential disruption of operations of a practice which conducts imaging operations in the same building, but in a different suite from where the practice provides physician services, CMS postponed the proposed January 1, 2008 effective date of the revised anti-markup rule, and indicated it would review the proposal during 2008.

The 2009 PFS contains a revised version of the anti-markup rule. Although CMS clearly wants to restrict the provision of imaging services by physician groups, it is apparently still unsure exactly how to proceed in this

continued, next page

area. After months of review and receipt of numerous comments, CMS has proposed two alternate approaches for revising the anti-markup rule, and seeks additional comments on its proposals and regarding "other possible approaches that would address our [CMS'] concerns regarding over-utilization motivated by the ability of a physician or physician organization to profit from diagnostic testing services."

Under the first proposal, the anti-markup rule would apply where the professional component or the technical component of a diagnostic testing service is either (i) purchased from an outside supplier, or (ii) performed or supervised by a physician who does not "share a practice" with the billing physician or physician organization. A physician is deemed to "share a practice" with the billing physician or physician organization only if the subject physician is employed by or contracts with a single other physician or physician organization. A radiologist who contracts to provide professional radiology services for several physician groups, for example, would not be considered to "share a practice" with any of such groups.

Alternatively, CMS proposes to maintain much of the current regulation and its "site of services" approach and apply the anti-markup provision to diagnostic tests that are performed outside the "office of the billing physician or other supplier." CMS proposes to clarify that the "office of the billing physician or other supplier" includes space in which diagnostic testing is performed that is located in the same building in which the billing physician or other supplier regularly furnishes patient care. This proposal is more in line with the exception contained in the Stark Law which permits a physician group to provide ancillary services if such services are provided in the same building in which the group provides physician services. This proposal, if adopted, would, however, prohibit a group practice which provides imaging services in a "centralized building," as currently permitted under the Stark Law, from marking up the cost of providing such services, unless the group also provides a full range of physician services in such centralized building. If a group is prohibited from marking up the cost of a particular ancillary service, it is economically infeasible for the group to provide such service for its patients.

In addition to soliciting comments as to which approach it should take with respect to revising the anti-markup rule to address over-utilization of diagnostic services by physician groups, CMS is soliciting comments on whether the proposed rule should become effective on January 1, 2009, or whether the effective date should be further delayed.

Conclusion

The charges discussed above are proposals. CMS expects to publish the final 2009 PFS rule by November 1, 2008. CMS does not always finalize every proposal it publishes. Regardless of what CMS ultimately decides regarding the anti-markup rule and application of IDTF standards to physicians, it is likely the final 2009 PFS will significantly restrict the ability of physician groups to provide imaging services for their patients.

(Endnotes)

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The Florida Bar Health Law Section Congratulates

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Martin Robert Dix, Tallahassee
Grant P. Dearborn, Tallahassee
Linda H. DuPuis, Tampa
and
Yvonne Gail Grassie, Miami

all, certified in Health Law as of August 1, 2008.

New Health Law Section CLE Program! Fundamentals of Health Law

Leadership of the Health Law Section is planning a new CLE program: Fundamentals of Health Law. The program will be designed to acquaint new members of The Florida Bar with Health Law in Florida. The program will be a refresher for those who have been away from Health Law and need brushing up.

Contact Chet Barclay at James.Barclay@Ruden.com or 850-412-2000, to help plan, organize, market or present a topic at this new exciting Health Law Section CLE program.

Program topics under initial consideration include:

Acute care
Administrative Procedure Act
Agency for Health Care Administration
Antikickback
Antitrust
Certificate of Need
Compliance
Department of Health
Division of Administrative Hearings
Emergency rooms
EMTALA
False claims
Governance
HIPAA
Hospice
Independent and assisted living
Insurance
Intensive/critical/transitional care
Legal ethics
Managed Care
Medicaid
Medical staff contracting
Medical staff credentialing
Medicare
Mental health care
Patient Safety
Peer review
Provider liability
Psychiatric care
Skilled nursing facilities
State regulation
VA

Your suggestions about different and additional topics are welcome.

There's a lot more about this Program that needs to be decided. Nothing is set in stone and everything is on the table. Here is what is envisioned at this early planning stage:

- *At least a one-day live program, probably in September 2009, during the Bar's Mid-Year Meeting.*
- *The one-day program may also be presented via the internet and will certainly be presented via video.*
- *Appropriate CLE credit will be offered.*
- *All presentations will be contained in materials, with PowerPoint slides.*
- *All PowerPoint presentations will have at least one animated slide.*
- *Modest registration fee that includes materials, luncheon and membership in Health Law Section.*
- *Keynote and luncheon speakers.*
- *Marketing to other sections, other organizations, law schools through the HLS website, and the Florida Bar News.*

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