

HEALTH LAW MONITOR

PUBLISHED BY THE LAW FIRM OF FELHABER, LARSON, FENLON AND VOGT, P.A.

Issue No. 5

Winter 2001

What is the Stark Reality?

by Jennifer A. Brooks

On January 2, 2001, part one of the Stark II final regulations was published in the federal register; further establishing that this law, which seemed entirely surreal to many of us when it initially was passed, appears to be a fact of life for physicians and health care providers that isn't going away. As the effective date for the final regulations (January 4, 2002) nears, we can expect stepped up enforcement of this law. In fact, the Justice Department, in a letter to Representative Stark, the original author of the Stark law, has stated that the government has over 50 cases of suspected Stark violations under investigation at this time. Now more than ever it will be important for physicians and health care providers to review their current financial arrangements and make certain they

fit within the regulatory requirements of Stark II. With that in mind, let's take a reality check to determine "What is the Stark reality?"

Reality Check Number 1

Stark II appears to be here to stay. The Stark II law has been in effect for over 7 years now, but part one of the final regulations (published on January 4, 2001) brings with it the likelihood of greater scrutiny by the Office of the Inspector General (OIG) of transactions between physicians and entities to which they make referrals for designated health services (DHS). If the Stark II final regulations are not repealed* (which appears unlikely), the OIG proposes to begin enforcement under the new regulations as of January 4, 2002. Until then, it would appear that the OIG has the right to enforce (and has been enforcing) the Stark II statute, as currently interpreted.

Health care entities and physicians will have the next several months to plan their contracting to assure compliance using the new interpretations presented in the final regs.

Reality Check Number 2

Stark II is designed to prevent over utilization of DHS but it is a very broadly drafted law. Stark II was passed to regulate self referrals by physicians to entities in circumstances where the physicians (or their immediate family members) stand to benefit from the referral, thus leading to the temptation for over utilization. Stark II is not a criminal law, as is the anti-kickback law. It is a preventative statute with severe civil penalties. Generally speaking, no intent is required to violate this law; and even well meaning parties may be in violation of the law.

Reality Check Number 3

It is unlikely that Stark II will be repealed in its entirety. Many lawyers and health care providers have been hoping that Stark II would be repealed. Although there has

Continued on page 3

**President Bush issued an executive order postponing enactment of many final regulations including Stark II. It seems unlikely, however, that these regs will be permanently placed on hold, since the action by Bush was not specifically directed at the Stark II regulations but was an executive action designed to give new agency heads time to review all regulations prior to their effective date.*

■ WHAT'S INSIDE ■

- Attention All Tax Exempt Health Care Organizations:
Has Your Organization Updated its
Conflicts of Interest Policies? Page 2
- NEWS: STAT! Page 2
- Felhaber Launches New Web Site Page 4
- Get Hopping – HIPAA'S Here! Page 5

Felhaber Larson Fenlon & Vogt

Attention All Tax Exempt Health Care Organizations: Has Your Organization Updated its Conflicts of Interest Policies?

by Jennifer A. Brooks

As you know, having a conflicts of interest policy is one of two factors considered by the IRS in determining whether hospitals or other health care organizations satisfy the IRS "community benefit" standard for remaining tax exempt. In 1997, the IRS published a sample conflicts of interest policy for tax exempt health care organizations which contained a definition of conflicts of interest, provided procedures for analyzing whether a conflict exists and a procedure for addressing conflicts. After receiving community comments regarding the 1997 sample policy, the IRS has now published an update with comments and suggested revisions to its prior 1997 sample policy.

The revised policy contains changes which are designed to clarify the IRS position and to make implementation of the policy easier for the parties involved. All tax exempt organizations should review their current conflicts of interest policies taking into consideration the most recent amendments to the IRS sample policy. The IRS has clarified the following points in its suggested amendments:

1. Every financial interest does not automatically translate into a conflict. The 1997 draft language provided by the IRS seemed to imply that a financial interest resulted in a conflict of interest. The IRS is now clarifying that all

financial interests are not automatically conflicts. The organization will want to revise its policy to clarify that a person having a financial interest does not necessarily have a conflict of interest. The organization's governing board has the responsibility to determine whether the financial interest of an interested person rises to the level of a conflict of interest.

2. The interested person should be given an opportunity to present his/her position to the Board. The 1997 draft policy indicated that the interested person was required to leave the room upon disclosure of a conflict of interest. This didn't appear to provide the board with the opportunity to gain input from the interested person which was necessary to the board's decision. The revised policy clarifies that the interested person should be given an opportunity to disclose all material facts relating to his/her financial interest before the governing board makes a determination of whether the person's financial interest rises to the level of a conflict of interest. This revision appears to give the interested person freedom to stay in the meeting for the time necessary to address questions and to disclose all material facts. The IRS still requires the policy to state that the individual must leave the room during the time the board is discussing whether a conflict exists and is voting on the matter.

Continued on page 6

NEWS: STAT!

HHS released the long-awaited final privacy regulations on December 28, 2000. The compliance deadline is April 14, 2003 (April 14, 2004 for small health plans).

On January 10, 2001, the **IRS released its temporary regulations on intermediate sanctions** for transactions of tax-exempt organizations. These regulations are effective January 10, 2001 through January 9, 2004.

HCFA released the final SCHIP (State Children's Health Insurance Program) rules on January 11, 2001.

been talk about repealing Stark II, there are no serious proposals being presented in Congress for a complete repeal of the law. The most conservative bill only calls for a repeal of the prohibition on compensation arrangements (as opposed to ownership arrangements which would remain subject to regulation). Representative Bill Thomas, the author of this bill, has stated that “completely repealing Stark II isn’t the answer because ownership situations pose a real risk of fraud and abuse.”

Reality Check Number 4

The potential penalties under Stark II must be a concern for all health care entities and physicians. The penalties under Stark II are potentially disastrous for health care entities and physicians. If referrals violate Stark II, the parties are required to reimburse Medicare and Medicaid for all amounts collected as a result of such referrals. In addition, substantial fines, for both the physician and the health care entity, of up to \$15,000 for each prohibited referral can be imposed, including a fine of up to \$100,000 in certain egregious circumstances. Most importantly, both the physician and entity may be excluded from Medicare and Medicaid.

Reality Check Number 5

Stark II penalties have no relationship to the actual financial consideration flowing between the parties. For example, if a surgeon is leasing a small amount of space in its building to the hospital, and the lease fails to meet the lease exception requirements of Stark II, (the lease isn’t in writing, doesn’t specify the leased space, is for more than fair market value, or uses a variable lease rate) every referral the surgeon makes to the hospital for designated health services (which includes all inpatient and outpatient hospital services) is in violation of Stark II. This is true whether the lease payment amount is \$50 dollars a month or \$5000 dollars a month and this is true

regardless of whether there is any intent to violate the law.

Reality Check Number 6

Part one of the final regulations contains several changes which will require a re-analysis of transactions over the next year. Here is a list of some of the major changes included in part one of the final regs:

- a. **Common Ownership in a Non-DHS Entity Equals Financial Arrangement.** This is a major change and requires a reanalysis of any transaction in which a physician (or physician’s family members) shares a common ownership in a non-DHS entity with the entity furnishing DHS. In the proposed regs common ownership did not create a compensation arrangement between the referring physician and the DHS entity. (For example, a hospital’s and physician’s group’s joint ownership in a real estate venture did not trigger Stark II analysis.) However, the final regs result in a complete reversal of this position. If health care entities and physicians have such joint financial relationships, they will want to consult with their attorneys prior to January 4, 2002 to allow for a review and restructuring of such transactions.
- b. **Group Practice Definitions.** The group practice definition has been expanded to include multi-entity legal structures provided there is one identifiable legal entity that is a bona fide group practice of two or more physicians. If your group practice arrangement didn’t fit under the group practice definition under the proposed regulations, you should revisit this issue under the final regulations.
- c. **In Office Ancillary Services Exception.** The final regs significantly broaden the in-office ancillary services exception by

conforming the supervision requirements to the requirements for HCFA coverage and payment policies for the services, and by expanding the DHS which may be provided under the in-office ancillary services exception.

- d. **Elimination of Group Practice Attestation.** The final regs eliminate the physician group practice written attestation required to qualify as a group practice under the proposed regulations.
- e. **New Definition of Designated Health Services.** The final regs change the statutory definition of DHS (in certain categories) to cross reference Medicare Current Procedural Terminology (CPT) Codes and HCFA Common Procedure Coding System (HCPCS) Codes hopefully making it easier to determine what constitutes a DHS within the categories covered.
- f. **New Knowledge Element of Indirect Financial Arrangements.** Under the final regs an indirect ownership or investment interest exists only if the entity furnishing the DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of the fact that the referring physician (or immediate family member) has some indirect ownership or indirect investment interest in the entity furnishing the DHS. (The proposed regs contained no knowledge requirement.) The comments suggest that entities obtain a certification of compliance from physicians to avoid being held liable under a “deliberate ignorance” standard.
- g. **New Interpretation of Volume or Value Standard.** The final regulations provide an interpretation of the “volume or value” standard permitting unit of service or time based payments so long as the unit

of service or unit of time based payment is fair market value, does not vary over time, and meets the statutory requirements.

h. New Exception for Indirect Compensation.

HCFA has created a new exception which protects an indirect compensation arrangement, provided the arrangement meets all of the statutory requirements.

i. Ignorance Exception for the DHS Entity.

The final regs create a new exception for entities submitting claims for DHS that did not know of and did not have reason to suspect the identity of the physician who made the DHS referral to the entity. Of course, entities will not want to "plan" on using the "ignorance exception" since the law will undoubtedly require a certain amount of vigilance by the health care entity to assure compliance with the law.

j. Non-monetary Compensation up to \$300.

Up to \$300 in non-monetary compensation per year would be exempt from Stark II under the final regs provided the compensation is not determined in consideration of the volume or value of referrals or other business generated by the referring physician, and is not solicited, directly or indirectly, by the physician.

k. New Fair Market Value Exception.

There is a new fair market value (FMV) exception to compensation arrangements which will provide greater flexibility than the current exceptions. As with all the majority of the exceptions, however, there are specific requirements imposed which must be met, such as having a written agreement, signed by the parties in advance of the arrangement.

l. Medical Staff Incidental Benefits Exception.

There is a new incidental benefit

(\$25 per each benefit) exception under the final regs for medical staff benefits provided by the hospital.

m. New Exception for Compliance Training.

Hospitals will now be allowed to provide free compliance training to physicians who practice in the hospital's local community or service areas, if the training is held in the local area (that is the hospital can't fly everyone to Las Vegas for compliance training.)

The Stark Conclusion

The Stark II final regulations (part one) are here. Part two should be available within the next several months. Repeal of the law is unlikely. We can expect to see enforcement of the law intensified after the final regulations become effective on January 4, 2002. In the interim, physicians, hospitals and other health care entities that receive referrals from physicians for DHS should re-examine their current transactions to make certain that they are all properly documented in a written agreement which meets the Stark II requirements. To the extent that such transactions are not properly documented, the parties will need to determine what is required to revise the documentation to fit within an exception under Stark II. If the transaction cannot be structured to fit within a Stark II exception, the parties will need to discontinue either the financial arrangement or the submission of claims for DHS to Medicare and Medicaid based on referrals from the physician or physician's group. ■



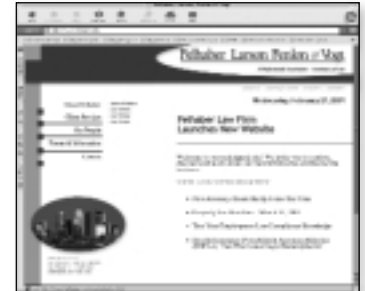
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Felhaber Law Firm Launches New Web Site!

At Felhaber, Larson, Fenlon and Vogt, we carefully considered the needs of our clients when we took on the task of improving our Web site. The priorities quickly sorted themselves out: practical information that is easy to find and use.

At the same time, we wanted to make the most of the Web environment through interactive features like searches.

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Get Hopping – HIPAA’S Here!

by Janet A. Newberg

The U.S. Department of Health and Human Services (HHS) issued the long-awaited final privacy regulations on December 20, 2000, and a lot of businesses that use or disclose medical information have a lot of work to do to get ready for HIPAA D-Day – April 14, 2003.

Congress passed the Health Insurance Portability and Accountability Act (HIPAA) in 1996. That statute called for, among other things, the development of comprehensive national medical record privacy standards. HHS published proposed regulations in late 1999, received tens of thousands of comments (some rather unpleasant) from the health care industry, and issued final regulations in December.

So, what do these new regulations require? In a nutshell, “covered entities” (health care providers, plans and clearinghouses) need to: (1) obtain patient consent to use or disclose individually identifiable health information for health purposes, (2) obtain patient authorization to use or disclose health information for non-health purposes, and (3) allow individuals to inspect and copy their health records, and request amendments to information they believe is incorrect. The HIPAA statute provides for both civil and criminal penalties for those covered entities that violate the privacy rules.

Although the privacy regulations are only directly applicable to the acts of “covered entities”, lots of other businesses will be indirectly affected. For example, businesses that provide services to health care providers and health plans and receive protected health information from the providers or plans, are “business associates” under the rule, and must have “business associate contracts” in place. Are you a hospital that hired a software consultant to help upgrade your patient billing system? You will need a business associate contract with the software consultant to make sure the consultant protects the privacy of health care information in the same way you must. Are you a health plan that needs outside counsel to help you defend a lawsuit brought against you by one of your insureds? You need a business associate contract with your outside law firm.

Employers are specifically excluded from the definition of “covered entity” under the privacy regulation. However, an employer can be an “employer” one minute, and a “covered entity” the next. If an employer has a self-funded health insurance plan, the “plan sponsor” meets the definition of a “health plan” – and, health plans are covered entities under HIPAA.

The plan sponsor part of the organization, as a covered entity under the privacy rules, can use and disclose protected health information under certain circumstances. The “employer” part of the organization, however, can’t use or disclose employees’ health information in the same way the plan sponsor can. Employers who also meet the definition of “health care provider” or “health plan” will have significant work ahead of them setting up the required policies and procedures for the protection of employee’s health care information.

Maybe the biggest HIPAA headache for the health care community involves the new right of patients to inspect and copy health care information pertaining to them, and to obtain an accounting of every single time their health care provider or plan disclosed all or part of their health information to someone else. Remember the hospital that hired the software consultant? The hospital must document whose patient information the software consultant saw while performing his work. How about that health plan that hired outside counsel to defend a lawsuit? The disclosure of that insured’s medical information to the attorney must be reflected on the health plan’s disclosure log.

Covered entities have a lot of work to do to make sure they are HIPAA-compliant by April 14, 2003, the final compliance date. Here is a list of the minimum tasks that must be completed in the next two years:

1. Designate a “Privacy Official”;
2. Develop privacy policies and procedures;
3. Develop an internal sanctions policy;
4. Prepare model consent forms;
5. Prepare model authorization forms;
6. Prepare a Notice of Privacy Practices and disseminate it as required;
7. Adopt policies and procedures to create and maintain a disclosure log;
8. Build “firewalls” to protect health information from improper disclosure; and
9. Train employees on your privacy policies and procedures.

Time’s flying. Get HIPAA-hopping! ■



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3. A board member cannot vote on his/her compensation. The IRS has clarified that an individual who is a voting member of the board and receives compensation from the corporation for services may not vote on any matter pertaining to that member's compensation.
4. Physician board members cannot vote on physicians compensation, whether his or her own compensation or another physician's compensation. The IRS policy still provides that a physician who is a voting member of the board of directors and receives compensation, directly or indirectly, from the corporation for services is precluded from discussing and voting on matters pertaining to that member's and other physician's compensation.
5. A physician may provide the board with information on physician's compensation. Although physicians cannot be part of the discussion or vote on

physician's compensation, the IRS policy expressly does not preclude or prohibit a physician or physician director, either individually or collectively, from providing information to the board of directors regarding physician compensation. They are simply prohibited from discussing or voting on compensation matters.

6. Physicians are prohibited from being a member of a compensation committee, but can provide information to the committee regarding physician compensation in general. The IRS has clarified that although a physician with a direct or indirect financial interest in a corporation may not be a member of a compensation committee, the physician may provide information to the committee regarding physician compensation in general. ■

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