



# HEALTH LAW

## Medicare Compliance: New OIG Guidance Helps Physicians

**T**he Office of Inspector General ("OIG") of the United States Department of Health and Human Services recently issued guidance to assist individual and small group physician practices in developing voluntary compliance programs that promote adherence to statutes and regulations applicable to Federal health care programs. The OIG's guidance represents a significant breakthrough in compliance planning for the smaller physician practice, by providing a clear road map for adopting a voluntary compliance program that can aid the practice in remaining in compliance with applicable statutes and regulations.

Following the OIG's recommendations in conjunction with IPA sponsorship and the use of template documents can significantly decrease the cost of compliance. Adopting such a compliance plan can also be a good investment for a physician practice. Case studies show that the better coding, documentation and awareness which comes from compliance education can actually increase practice revenues in North Carolina.

The Federal government has indicated in recent years that combating health care fraud and abuse is a top priority, and has committed significant resources to investigate and eliminate these problems. In addition, new legislation has been enacted and new regulatory mechanisms put in place to address such fraud and abuse. You may know that civil sanctions may be imposed each time an individual submits a claim for payment that he or she "knows or should know" is inappropriate and will fall into a prohibited category. Civil money penalties may amount to \$10,000 per claim (\$50,000 for an anti-kickback violation) plus an assessment of up to three times the amount improperly claimed. In addition, criminal penalties may be imposed when an individual "know-

ingly and willfully" defrauds the Medicare, Medicaid, or other Federal health care benefits program. Sanctions may include imprisonment for up to five years, fines, and exclusion from participation in government health care programs.

In this context, it is increasingly important for all health care providers to review their business practices for any actions that may be construed as fraudulent or abusive. Developing and implementing a Medicare Compliance Program will help providers monitor adherence to applicable statutes, regulations, and program requirements, and will help reduce the likelihood of government sanctions. Furthermore, the Federal government has indicated that it will consider the existence of a compliance program when making determinations as to whether a medical practice or other health care provider has made reasonable efforts to avoid and detect misbehavior.

The OIG suggests that a voluntary compliance program include the following components:

- Conducting internal monitoring and auditing through the performance of periodic audits
- Implementing compliance and practice standards through the development of written standards and procedures
- Designating a compliance officer or contact(s) to monitor compliance efforts and enforce practice standards
- Conducting appropriate training and education on practice standards and procedures
- Responding appropriately to detected violations through the investigation of allegations and the disclosure of incidents to appropriate governmental entities
- Developing open lines of communication such as discussions, staff meetings, and community bulletin boards to keep practice employees updated regarding compliance

activities and how to avoid erroneous or fraudulent conduct

- Enforcing disciplinary standards through well publicized guidelines

These components provide a solid basis upon which a physician practice can create a compliance program. The OIG acknowledged in its guidance that full implementation of all components may not be feasible for all practices, and that some practices may never fully implement all the components. However, the OIG indicated that a practice can begin by implementing the components that are most likely to provide an identifiable benefit, based on a practice's specific history with billing problems and other compliance issues. The extent of implementation will depend on the resources of the practice. The OIG predicts that better compliance in billing and documentation may well have a material upside economic benefit to a practice through fewer denials and underbillings.

In response to client requests, we have developed a program for small to medium sized practices to develop and implement Medicare Compliance Programs in accordance with the OIG's guidance. These compliance programs can be highly cost-effective for individual physician practices, especially in contexts where a number of practices are participating through IPA sponsorship. In addition, these programs are tailored to meet the specific needs of each individual practice. Working in conjunction with Rose Shattuck at Larson Allen - Cherry Bekaert, physician practices receive a complete compliance program solution, including a baseline compliance audit, follow-up seminars with physicians and staff, implementation of compliance program standards, procedures and protocols, and ongoing updates. For more information, please contact Bo Bobbitt (bbobbitt@smithlaw.com, 919-821-6612) or Paul Barringer (pbarringer@smithlaw.com, 919-821-6753).

# HIPAA Planning for Medical Practices

Physicians will hear a lot about "HIPAA" over the next few years. The "administrative simplification" provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") will have dramatic effects on physician practices. The HIPAA-required standard formats and code sets for electronic transactions can substantially reduce overhead costs associated with health claims and health coverage transactions (real-time, electronic plan eligibility verifications alone will be a nice "plus").

Physicians will not be required to submit claims electronically, but if they do submit electronic claims, they will be required to do so by October 16, 2002 in the standard formats and code sets or to use a "clearinghouse" to convert the transactions to the standard formats and code sets. There are over 400 different versions of electronic health claims today, but HIPAA establishes one set of national standard transaction formats for covered entities.

Physicians who do submit electronic claims will also have to comply with privacy and security rules of the United States Department of Health and Human Services. The final privacy rule was published in the Federal Register on December 28, 2000 and has a compliance deadline for physicians of April 14, 2003. The final HIPAA security rule is expected to be issued later this year.

Although most physicians and their offices take patient confidentiality very seriously, the privacy rule will require substantial changes in current operating practices for virtually all physician practices. Failure to comply can result in criminal penalties. Knowingly disclosing individually identifiable health information in violation of HIPAA can result in a fine of up to \$50,000 and one year in imprisonment; if there is a motive to disclose the information for personal gain or commercial advantage, the penalty is increased to a fine of up to \$250,000 and up to ten years imprisonment.

Medical practices will need to establish, implement, and document written policies and procedures in a variety of areas required by the privacy rule with respect to uses and disclo-

tures of protected health information. To name a few examples, policies and procedures will be required for:

- Obtaining required written consents from patients.
- Establishing what are "minimum necessary" uses and disclosures of protected health information and requests for protected health information from other covered entities.
- Employee and contractor sanction policies for the noncompliance with privacy policies and procedures.
- Appointing a chief privacy officer.
- Providing notices of information practices to patients.
- Training of employees.
- Managing required written contracts with "business associates".

Given the magnitude of what it will take to comply with the HIPAA rules, two years is not a lot of time to design, build, and implement a compliance plan.

How should physicians manage this new compliance process?

First, physician leaders in a practice need to understand HIPAA and its implications and then establish the practice's policy that HIPAA needs to be taken very seriously and the practice will do what it takes to comply. Look to medical practice-specific guidance which has "tailored" the requirements to the unique setting and limitations of your office environment.

Second, the practice should obtain an evaluation of how the HIPAA rules apply to the specific practice, and what the "gap" is between current policies and procedures and those that will be required under HIPAA.

Third, the practice will need to develop a HIPAA compliance plan, including the numerous policies and procedures referenced above. Fourth, the practice will need to conduct training for all affected employees.

Finally, the practice will need to manage the implementation of the compliance process on an ongoing basis and continually document its compliance with the many specific requirements.

Start talking now with your technolo-

gy vendors and business associates about HIPAA. Do not assume that they are working toward compliance. The following are some good initial questions to ask your vendors:

- Does the vendor know what HIPAA is and can they demonstrate an understanding of its requirements?
- What are the "clearinghouse" arrangements with your practice management system vendor to convert your electronic transactions into the required standard formats and code sets?
- If the vendor's application uses the Internet, does it contain encryption technology? If encryption is used, how does this affect the application and your network?
- Will the vendor provide enhanced privacy and security features to ensure HIPAA compliance? When will the enhancements be available?
- How have the enhancements been tested and how will the "test to production" migration path be scheduled and handled?
- Are the enhancements included within the scope of normal maintenance agreements and as part of the application or hardware upgrade cycle? If not, what are the additional costs associated with the enhanced features?
- Will the security enhancements increase the complexity of the application or system? If so, will the vendor provide additional support and training?

HIPAA is coming. What are you doing to prepare?

For more information regarding HIPAA, contact Bo Bobbitt (bbobbitt@smithlaw.com, 919-821-6612) or Mike Hubbard (mhubbard@smithlaw.com, 919-821-6656).



# HCFA PUBLISHES PHASE I OF FINAL STARK RULE

Many medical practices received some good news on January 4, 2001, when the Health Care Financing Administration ("HCFA") published Phase I of the final Stark II rule. In significant departures from the January 8, 1998 proposed Stark II regulations, HCFA's revised rule will allow some group practices greater flexibility in structuring their compensation plans, while still allowing those practices to take advantage of the in-office ancillary services exception to the statutory prohibition on self-referrals.

## THE STARK LAW

The Stark law prohibits physicians from referring Medicare or Medicaid patients for certain "designated health services" (including laboratory services and radiology services, among others) to an entity with which the referring physician or a member of the referring physician's family has a financial relationship, unless an exception applies. For example, a physician would not be able to refer a Medicare patient to a diagnostic center that the physician owns, unless the physician's ownership fits an exception.

One of the most important and frequently used statutory exceptions to the referral prohibition is the "in-office ancillary services" exception. This exception permits a physician to refer Medicare or Medicaid patients for certain designated health services within the referring physician's own group practice, provided that certain conditions apply. For example, a physician can, subject to certain conditions, refer Medicare or Medicaid patients to his or her own group practice's x-ray machine. However, only practices that satisfy the statute's definition of "group practice" may take advantage of the in-office ancillary services exception.

To be a "group practice" under the statute, a practice may not pay compensation based directly or indirectly on the volume or value of referrals by any physician, except that a physician member of a group practice may receive a share of the overall profits of the group, or a productivity bonus based on services personally performed by the physician or services incident to such personally-performed services, so long as the share or bonus is not determined in any manner which is directly related to the volume or value of referrals by the physician.

## JANUARY 8, 1998 PROPOSED RULE

In its proposed rule implementing the Stark II statute, HCFA interpreted the group practice compensation requirements very strictly, so that many common group compensation arrangements would not have met the group practice definition. The important consequence of failing to qualify as a group practice is that none of the members of the practice can take advantage of the in-office ancillary services exception (e.g., a physician cannot refer patients to the group's own x-ray machine).

## JANUARY 4, 2001 PHASE I FINAL RULE

In its Phase I final rule, HCFA revised its definitions of "referral" and of "group practice," which will increase many group practices' flexibility in creating compensation plans.

HCFA revised its definition of "referral" so that a referral consists only of designated health services that are not personally performed by the referring physician. This definition has an important effect on the development of compensation schemes. Where HCFA had previously indicated

that productivity bonuses based on personally performed services must exclude designated health services from such personally performed services, now personally performed designated health services may be included in the productivity bonus calculation. However, a group practice may not include services incident to a physician's services in the productivity calculation.

The final rule also provides helpful specific examples of acceptable distributions of the overall profits of the group and of acceptable productivity bonuses. These examples will lead to greater clarity in determining whether a group practice qualifies to take advantage of the in-office ancillary services exception.

However, HCFA giveth and HCFA taketh away. The location requirements under the in-office ancillary services definition have been narrowed. Now, in order to satisfy the exception's requirement that designated health services be provided in the same building as other physician services, "the same building" must be a structure or combination of structures with a single street address. HCFA has also revised the in-office ancillary exception's location requirement for designated health services provided in a centralized building. The key change is that the space must be used by the group practice on an exclusive, full-time basis for a period of at least six months.

## CONCLUSION

The Stark II Phase I final rule should increase most medical practices' flexibility with respect to structuring internal compensation plans. For more information, please contact Sean Timmons (stimmons@smithlaw.com; 919-821-6709).

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## SMITH ANDERSON'S HEALTH LAW GROUP

Paul Barringer  
*pbarringer@smithlaw.com*

Bo Bobbitt  
*bbobbitt@smithlaw.com*

Susan Hargrove  
*shargrove@smithlaw.com*

Michael Hubbard  
*mhubbard@smithlaw.com*

Dana Simpson  
*dsimpson@smithlaw.com*

Sean Timmons  
*stimmons@smithlaw.com*

Robin Vinson  
*rvinson@smithlaw.com*

2500 First Union Capitol Center ~ Raleigh, North Carolina 27602  
**Telephone:** 919-821-1220 ~ **Telecopies:** 919-821-6800 ~ **E-Mail:** Info@smithlaw.com

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**SMITH ANDERSON**

P.O. Box 2611  
Raleigh, NC 27602-2611