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April 27, 2010

Marilyn Tavenner  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
PO Box 8011  
Baltimore, MD 21244-8018

**RE: Disclosure of ownership information by physician practices providing radiology services using the in-office ancillary services exception to the physician self-referral law**

Dear Ms. Tavenner:

The practice of medicine has changed greatly in the last 10 years. Today's technology has progressed significantly and brought with it new advances in cardiovascular practice. Once ancillary, imaging devices are now critical to diagnosing and treating cardiovascular conditions and are integral components of cardiovascular practice. When used appropriately, these devices are powerful tools in a cardiologist's arsenal for diagnosis and treatment of cardiovascular disease.

The American College of Cardiology (ACC) is a professional medical society and teaching institution made up of more than 38,000 cardiovascular professionals from around the world – including 90 percent of practicing cardiologists in the United States and a growing number of registered nurses, clinical nurse specialists, nurse practitioners, physician assistants and clinical pharmacists. The ACC supports physician ownership in facilities, equipment or services that benefit patients through the delivery of appropriate, high quality, medical care. Given the importance of imaging services to cardiovascular practice, this support extends to imaging-related equipment.

#### General concerns

The Patient Protection and Affordable Care Act of 2010 (PPACA) includes requirements that have the potential to increase the burden on physician practices furnishing these imaging services. Title VI of PPACA contains a number of provisions that focus on maintaining the integrity of federal health benefits programs, including closing perceived loopholes in the physician self-referral (Stark) law. **The ACC urges CMS to implement these provisions in a manner that minimizes the costs and administrative burdens on cardiovascular practices struggling to keep their doors open, despite declining reimbursements and difficult economic conditions.** It is in this vein that the College makes the recommendations below.

*The mission of the American College of Cardiology is to advocate for quality cardiovascular care — through education, research promotion, development and application of standards and guidelines — and to influence health care policy.*

## Specific concerns

### Medicare self-referral disclosure protocol

The Stark law was originally established as a “bright line rule” prohibiting referrals to entities furnishing certain services in which the referring physician or an immediate family member held a direct or indirect financial interest. Today, that bright line rule has numerous exceptions with countless tests and technicalities that must be followed. Any failure to comply with one of those exceptions strictly could be considered a violation of the law, no matter how inadvertent. Cardiovascular professionals do their best to navigate this highly complex regulatory schema, hiring attorneys, fair market value assessors and other professionals in order to provide critical services to their patients.

Given this level of complexity and the potential for harsh penalties for violations, regardless of intent, any change to the Stark law immediately raises concerns and fears in the physician community. **Given the complexity of the law and the ease with which it is possible to commit an unintentional violation of it, the ACC implores CMS to move quickly in establishing the regulations and a process for implementing Sec. 6409 of PPACA.** Under Sec. 6409, the Secretary is required to establish a protocol for physicians to self-disclose violations of the Stark law. Additionally, the Secretary is permitted to reduce the monetary penalties for such violations after taking into account a variety of factors relating to the offense.

Most cardiovascular professionals, and physicians generally, do not set out to violate the Stark law. Instead, the violations committed are typically inadvertent and constitute merely technical violations of the law. When the violations are discovered, physicians are left in a difficult position: disclose the violation and suffer the consequences or remain silent and fear discovery. **The ACC recommends that CMS create a self-disclosure protocol that alleviates these concerns by allowing physicians to remedy technical violations, such as a missing signature, with little to no penalties, and permitting physicians to repay any amounts collected as a result of the inadvertent violations, where appropriate, with resulting penalties adjusted based on circumstances and ultimate harm.** After all, it should not be the government’s aim to prosecute and potentially exclude physicians who have unintentionally violated a highly complex law from participation in the Medicare program. Instead, the taxpayers are best served when the government spends its allocated funds on identifying and eliminating those who intentionally seek to defraud it and to deplete the Medicare trust fund. For cardiologists, exclusion from the Medicare program has the potential to end their careers, given the large number of cardiology patients covered under the Medicare program. **Thus, the ACC urges CMS to avoid establishment of a protocol that does not provide reasonable allowance for difficulty understanding the highly complex regulatory schema that has developed in this area. Instead, the protocol should provide leeway for those who have attempted to comply, believed to a reasonably degree of certainty that they were, in fact, in compliance, and reasonably seek to remedy the situation when they determine a violation has been committed.**

### Disclosure of ownership interests

Some of the changes made by PPACA to the Stark law aim to limit the exceptions to the law, potentially requiring modifications to the organizational structure of many cardiovascular practices and increasing the costs and administrative burdens on their operations. Specifically, Sec. 6003 of PPACA requires physician practices whose owners have ownership or financial interests in an entity furnishing radiology services meeting the definition of “designated health

service” (DHS) under the in-office ancillary services exception to the Stark law to provide patients being referred for such services with a list of alternative sources of these services. A number of questions arise from this provision.

The ACC supports providing patients with information regarding the ownership of facilities, equipment or services that benefit patients through the delivery of appropriate, high quality, medical care. In fact, it is the policy of the ACC that physician ownership must also be clearly disclosed and transparent to all patients using these facilities.

([http://www.acc.org/advocacy/advoc\\_issues/physician\\_ownership\\_policy.cfm](http://www.acc.org/advocacy/advoc_issues/physician_ownership_policy.cfm)) As such, these recommendations are in no way offered to interfere with or hinder that goal. Instead, they are intended to assist CMS in crafting a policy that provides patients with information in a manner that confers the least burden on physicians and the practice of high quality medicine.

#### *Effective date*

According to the law, this provision is retroactive to Jan. 1, 2010. Thus, technically, it is in effect today. Given the statutory language, practices are confused as to whether they are expected to retroactively notify patients referred for such services earlier this year with lists of alternative sources of the services. Clearly, this does not make much sense, but this would seem to be what is demanded by the letter of the law. **The ACC urges CMS to address the issue of the effective date in short order to quell concerns from cardiovascular practices eager to comply with federal law.**

#### *Applicability to services other than those specified*

Another area causing confusion among practices is the array of services covered by this provision. After all, the law leaves it to the Secretary to determine exactly what radiology services are affected, other than magnetic resonance imaging (MRI), computed tomography (CT), and positron emission tomography (PET). Given that this is new and uncharted territory, **the ACC urges CMS to limit the applicability of this requirement to only those services explicitly listed in the statute: MRI, CT and PET.** To expand the application of the provision beyond the named services would only add to the confusion and increase any negative effects on physician practices. Additionally, this requirement has the potential to be hugely burdensome for physician practices, depending on how it is implemented. By limiting the effects to those services explicitly named in the statute, the burden can be minimized and targeted at those services.

MRI, CT and PET services are offered at a limited number of locations, whereas many of the other services are far more widespread. It will be easier and less burdensome to generate lists of providers of those three services than it will be a number of the other services classified as “radiology services.” Lists of providers of many of the other radiology services have the potential to be endless, depending on the environment in which the practice operates. While ACC believes that physicians providing the other radiology services should furnish their patients with information regarding ownership, **the College recommends that CMS continue to allow them to disclose those ownership interests in a manner chosen by the physicians rather than by legally defined protocols.**

#### *Quality of care and access concerns*

Ensuring that patients receive high quality healthcare is of great concern to cardiovascular professionals, and the ACC is committed to providing cardiovascular professionals with the information and tools needed to furnish appropriate, quality care to their patients. This includes

the establishment of appropriate use criteria for diagnostic imaging services furnished by cardiovascular professionals and a host of other tools and publications designed to enhance the quality of care that patients receive.

Because of this emphasis on quality, cardiovascular professionals refer their patients to others whom they believe also share this same vision, and patients view referrals from their physicians as endorsements of the physicians to whom they are being referred. Given this, cardiovascular professionals are concerned that any list of alternative sources of diagnostic imaging services provided from the physician to the patient could be seen as an endorsement of those providers. **Thus, the ACC recommends that CMS allow physicians to make it clear on any materials furnished to the patients as a result of this provision that there is no intended endorsement of the facilities named on the list.**

In addition to viewing referrals from their physicians as endorsements, patients tend to view information provided to them from their physicians as promises or certainties. In this case, that could translate into a guarantee that patients will be able to make an appointment with any of the imaging providers within the required period of time. However, there is no guarantee that the providers on the list will be accepting new patients. What is the obligation of the referring physician to ensure that the imaging providers on the list are accepting not just new patients, but new Medicare patients? How frequently must this information be verified? Ongoing verification requirements would be tremendously burdensome on physicians and their practices. **The ACC recommends that physicians not be required to update the lists more frequently than annually and that there be no obligation on the physicians to verify whether the providers on the list are accepting new Medicare patients.**

#### *Logistical concerns*

Another issue is the question of how physician practices are expected to compile such lists. Should they be conducting a search of the Internet or the telephone directory? If so, what in particular should they be searching for in order to ensure that they furnish patients with sufficient and actual alternatives? Will the Medicare contractors have a list of entities providing such services? And with respect to the list, what information should it contain – is contact information sufficient or is more detailed information required? In rural areas, the practice may be the only facility in the vicinity providing the DHS. For instance, there is only one cardiac PET camera in central Texas. Does this mean that the practice that owns this equipment must furnish information on facilities outside of central Texas who own this equipment to its patients? In urban areas, the list for providers of certain DHS has the potential to be quite extensive. How complete does the list need to be? The statute requires that the list of suppliers include those provide the services “in the area in which such individual resides.” How far does this area extend? Does this mean the list needs to be customized for each individual patient? And what about accuracy? How frequently does the list need to be verified and updated? **The ACC urges CMS to proceed with caution when drafting regulations and guidance on how practices are to compile the lists of alternate providers of the specified services. The area should be limited to a reasonable distance, fixed in scope and determined based on the practice location.** Otherwise, the administrative work associated with requiring private practices, already struggling with declining reimbursement and rising costs, to provide patients with customized lists requiring frequent updating would further burden them.

### *Issues relating to proper diagnosis and treatment*

Physicians are specifically trained to make determinations regarding diagnosis and treatment. This includes the types of diagnostic tests required to make those diagnosis and treatment plans. Thus, it is important that patients receive the specific test for which their physicians refer them. For instance, cardiologists generally refer patients for tests involving the use of a 64-slice CT. In fact, many states today require that these tests be performed using a 64-slice CT, as opposed to the 16-slice machines. However, it may not be clear from a imaging provider's website exactly what devices the provider has and what services the provider offers. **Given this, the ACC believes that it is critical for CMS to make it clear that the list of alternate sources is to be for the same service for which the patient has been referred and that CMS develop a standardized, consistent method for providing accurate information to patients.**

### *Recommendations*

To address many of the questions and concerns raised above, **the ACC urges CMS to create a publicly available database of providers of the specified services and maintain this information online and in the Medicare provider directory that is published annually.** In this way, patients could determine for themselves the area in which they reside and access the lists whenever needed. This database should allow patients to sort providers by zip code and cross state lines to allow patients who live near state boundaries to determine where services are more accessible to them. While the use of regional Medicare contractors does reduce the need for a centralized database, it does not extinguish it because there may still be patients who opt to seek services from providers outside of the jurisdiction in which the patient actually resides. The database should be based on data gathered from claims submitted by Medicare practitioners. By using this information, CMS should be able to determine available sources of the applicable designated health services. Beginning in 2012, CMS could use information from the approved accrediting organizations to determine the appropriate referral sources. Alternatively, CMS could begin using information from the approved accreditation organization to compile the lists, given that the organizations have already accredited a significant number of facilities in advance of the deadline. Using the information in advance to compile these lists could be an incentive to those organizations demonstrating an early commitment to furnishing high quality imaging services to patients.

Having a CMS-compiled list ensures that the list furnished to the patients is neutral and eliminates the endorsement question, relieving practices of liability concerns should the patient select a provider of lesser quality from the list. Additionally, this removes the burden of developing and maintaining the lists from practices. It should be less work for CMS to create this list than it is for practices, since much of this information can be gleaned from information already furnished by practitioners to Medicare. Another benefit to this is that patients would have a standardized process for locating the information, regardless of the test for which they have been referred.

**To assist physicians in complying with the notification portion of the provision, the ACC recommends that CMS draft a standardized notice to be given to patients.** The notice should contain information about the statutory requirement, the required disclosure and information of where patients can find the list of alternative referral sources. In this way, CMS can ensure that patients are given the information in a neutral, comprehensive and consistent manner.

**The ACC also recommends that CMS give special attention to those facilities that have already gone through the accreditation process.** Any list of alternate sources of the specified

services should give those practices that have already been recognized through the accreditation process as furnishing high quality CT, PET and MRI services should be given additional recognitions, whether as the only facilities on the lists of alternative sources or with a separate designation on those lists.

### **Conclusion**

Given the concerns raised above, prudent and vigilant cardiovascular professionals have already begun contacting the ACC for information and advice. However, without implementing regulations or guidance, there is little information to share with them. **The ACC urges CMS to swiftly issue guidance regarding enforcement of Sec. 6003 and implementation of the self-disclosure protocol required by Sec. 6409 to assist physicians in their attempts to comply with the law.**

The ACC appreciates the opportunity to provide these recommendations to CMS and would welcome the opportunity to work with the Agency on this and related issues. If you have any questions or concerns regarding these comments, please contact Lisa P. Goldstein at (202) 375-6527 or via e-mail at [lgoldstein@acc.org](mailto:lgoldstein@acc.org)

Sincerely,



Ralph G. Brindis, M.D., M.P.H., F.A.C.C.  
President

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