

New Patient Disclosure Requirements for Physician Offices Providing MRI, CT & PET Imaging Services

by Cori C. Turner, Esq. & Megan C. Phillips, Esq.

The regulations provide much needed guidance with respect to steps that physician practices may take to comply with the disclosure requirement.



The authors are attorneys with Husch Blackwell LLP. Cori C. Turner, JD, is a partner in the Kansas City, Missouri, office; and Megan C. Phillips, JD, is an associate in the Omaha, Nebraska, office. Husch Blackwell, LLP, serves as legal counsel to the MSMA. Contact: cori.turner@huschblackwell.com

Physician practices that provide in-office advanced imaging services such as MRI, CT, and PET scans should be aware of recent changes to the federal physician self-referral law (commonly referred to as the “Stark Law”) that will soon require certain patient disclosure practices.

The Stark Law prohibits physicians from referring Medicare patients for certain designated health services (“DHS”) to an entity with which the physician or a member of the physician’s immediate family has a financial relationship, unless an exception applies.¹ It also prohibits an entity from presenting or causing to be presented a bill or claim to anyone for DHS furnished as a result of a prohibited referral. One of the exceptions that many physician practices rely on is the “in-office ancillary services exception”, which generally permits physician practices to order and provide DHS (other than most durable medical equipment and parenteral and enteral nutrients) in the physician office, provided that certain criteria are met.² These include criteria related to who may provide the service, where the service may be provided, and who may bill for the service.

One of the many sweeping changes implemented under the recent health care reform legislation relates to an

additional requirement for compliance with the in-office ancillary services exception. In particular, Section 6003 of the Patient Protection and Affordability Care Act (“PPACA”) amended the Stark Law in-office ancillary services exception to require physicians referring patients for in-office MRI, CT, PET, or other radiology services that the Secretary of HHS may deem appropriate, to inform patients, in writing, at the time of the referral that the patient may obtain the services from a person other than the referring physician, a physician member of the same group practice as the referring physician, or someone directly supervised by the referring physician or another physician in the group practice. Section 6003 also requires the referring physician to provide the patient with a list of alternative suppliers in the area where the patient resides.³

While the health care reform legislation raised many questions regarding the form, timing, content, and effective date of the disclosure requirement, many of these questions have been addressed by the Centers for Medicare and Medicaid Services (“CMS”) in its proposed regulations implementing Section 6003. These proposed regulations, published by CMS on July 13, 2010, provide additional insight into the disclosure

requirement.⁴ While CMS is requesting comments on certain aspects of the regulations which may ultimately change, the regulations do provide much needed guidance with respect to steps that physician practices may take to comply with the disclosure requirement. In addition, CMS clears up ambiguities regarding the scope of services subject to the disclosure requirement and its effective date.

1. Services Subject to the Disclosure Requirement

As indicated above, Section 6003 provides that physicians referring patients for in-office MRI, CT, PET, or other radiology services that the Secretary of HHS may deem appropriate would be subject to the new disclosure requirement. While this left the door open for CMS to require disclosure for additional types of in-office radiology services, CMS indicated in the proposed regulations that it was not inclined to expand the disclosure requirement to other radiology services at this time. However, in the proposed regulations CMS solicited comments regarding this issue and, therefore, CMS may expand the list of services subject to the disclosure requirement beyond MRI, CT, and PET in the final regulations.

2. Timing of Disclosure

CMS indicated in the proposed regulations that the disclosure notice must be given to the patient at the time of the referral. CMS indicated that it was not proposing any exceptions to the disclosure requirement for MRI, CT, or PET services furnished on an emergency or time-sensitive basis. However, CMS requested comments on whether there were any circumstances that might warrant an exception to the requirement that the disclosure be provided prior to the provision of the imaging services.

3. List of Alternate Suppliers

According to Section 6003, the disclosure must include a written list of alternate suppliers who furnish the radiology services in the area in which the patient resides. CMS made several clarifying statements in the proposed regulations which should assist physician practices in complying with this requirement.

First, CMS proposed that the list does not need to include hospital providers of services. Instead, the list only needs to include physicians, practitioners, or other types of facilities enrolled as "suppliers" under Medicare. CMS did, however, request comments on whether hospitals or other providers of services should be included on the list and as such, this requirement may be subject to change in the final regulations.

Second, CMS acknowledged that requiring a physician practice to provide a list of suppliers in the area that the patient resides would be unduly burdensome, as many patients may travel outside of their immediate residential area for physician services. CMS indicated that it would be impractical for physician practices to develop different lists of alternate providers for different patients depending on where that patient lives. Therefore, CMS proposed that the list of alternate providers need only list suppliers that are located within a 25-mile radius of the physician office location. CMS reasoned that it has used a 25-mile radius in other exceptions to the Stark Law, and that it believed a 25-mile radius would be sufficient in most areas to generate a useful list of suppliers. However, CMS again solicited comments regarding whether the 25-mile radius would be sufficient, particularly in rural areas.

Third, CMS proposed that a physician practice must include at

least 10 alternate suppliers on the list. At this time, CMS has not proposed requirements regarding where those 10 suppliers may be located within the 25-mile radius described above. CMS indicated that it did not want to require physician practices to list the 10 closest suppliers, as it wanted to give physician practices some freedom in drafting the list. However, CMS also expressed concern that some physician practices may use the lack of definitive guidelines to draft a list of suppliers that are on the edge of the 25-mile radius, thereby suggesting to their patients that there are no other suppliers conveniently located near the physician practice. CMS requested comments on this issue, and whether or not there may be alternate criteria that could be used in developing an adequate list of suppliers. CMS also acknowledged that in certain areas, there may be less than 10 or no alternate suppliers at all in the 25-mile radius. In this circumstance, CMS proposed that the provider must still give the disclosure, however, the alternate supplier list would only need to include the suppliers within the specified radius.

4. Content of Disclosure

As indicated above, the disclosure notice must indicate that the patient may receive the MRI, CT, or PET services from another supplier, and must also specifically list suppliers in the area that are available to provide the radiology services. The proposed regulations also require that certain alternate supplier information be included in the disclosure, including the alternate suppliers' (i) name; (ii) address; (iii) phone number; and (iv) distance from the physician practice's office location. CMS also proposed that a record of the patient's signature on the disclosure notification must be maintained as an element of the patient's medical record.

5. Effective Date

Section 6003 created ambiguity regarding the effective date of the disclosure requirement under the in-office ancillary services exception. Although the PPACA was not enacted until March 23, 2010, Section 6003 appeared to retroactively implement the disclosure requirement effective as of January 1, 2010. This created confusion in the physician imaging industry, as it would have been impossible to comply with the disclosure requirement before physician practices were even aware of its existence. Nevertheless, many physician practices attempted to comply with the law immediately after March 23, 2010 with the hope that CMS would not enforce compliance with the disclosure requirement until after that date.

CMS has now cleared up the ambiguities regarding the effective date of the disclosure requirement by indicating that it has interpreted Section 6003 to mean that compliance with the disclosure requirement is not necessary until final regulations have been implemented by CMS. Therefore, CMS has clarified that physician practices do not need to comply with the disclosure requirement until January 1, 2011, which is the date CMS expects the final regulations to be implemented.

Despite the delay in effective date, physician practices should prepare their disclosure notices now to ensure that they have appropriate forms and procedures in place to comply with the disclosure requirement upon the implementation of the final regulations.

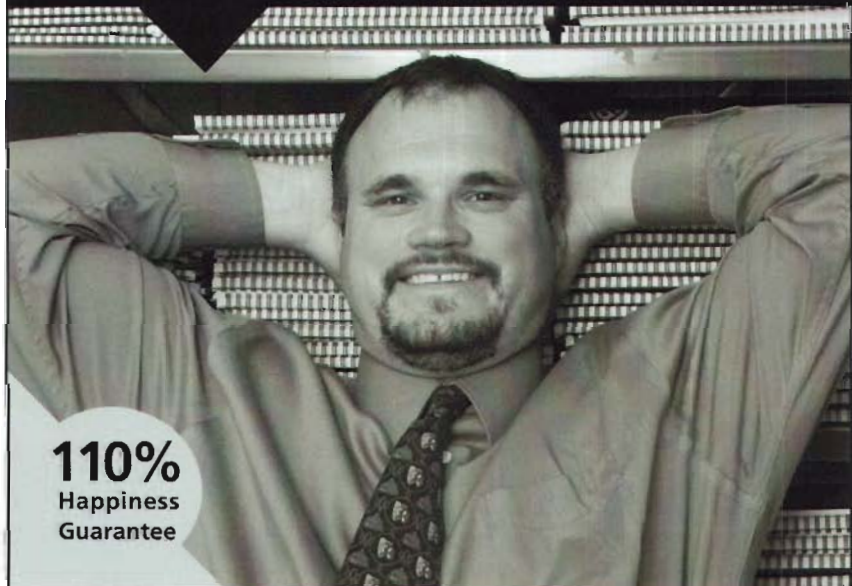
References

1. 42 USC § 1395nn.
2. 42 USC § 1395nn(h)(2); See also 42 CFR § 411.355(b).
3. Pub. L. No. 111-148, § 6003.
4. 75 FR 40040, 40140 (July 13, 2010).



“Socket combined voice, data and Internet for six office locations. I can finally take a real vacation.”

Jay Hall, Information Services
Missouri National Education Association
Jefferson City, MO



**110%
Happiness
Guarantee**

We work tirelessly to offer voice, data and Internet solutions that'll even impress an IT guy surrounded by lawyers and lobbyists.

Bundle your business voice, data and Internet and get Socket's 110% Happiness Guarantee. If you're not satisfied and cancel within 60 days, you'll get your money back—plus ten percent!



1-800-SOCKET-3 • www.socket.net