



Alert

Life Sciences and Health Care Client Service Group

To: Our Clients and Friends

December 16, 2010

CMS Issues Final Regulations Modifying Two Stark Exceptions

Last week, CMS issued final regulations that will change two important Stark exceptions: the in-office ancillary services exception and the physician owned hospital exception. These regulations result from changes made to both exceptions by the Patient Protection and Affordable Care Act ("PPACA").

In-Office Ancillary Services Exception

PPACA amended the Stark in-office ancillary services exception by imposing a new disclosure requirement when a physician refers a patient for certain imaging services performed or billed by the physician's group practice. With respect to referrals for MRI, CT, or PET services, PPACA requires that the referring physician inform the patient in writing at the time of the referral that the patient may receive the service from someone other than the physician and provide the patient a list of alternative suppliers. PPACA also gives CMS the power to require such a disclosure for radiology services in addition to MRI, CT, and PET services.

In its final rule, CMS elected to require disclosure only for MRI, CT, and PET services; it did not expand the disclosure requirement to other radiology services as permitted by law. Furthermore, the final rule specifies that the written notice must include a list of at least five other suppliers that provide the services for which the patient is being referred within a 25-mile radius of the physician's office location at the time of the referral. The notice must include, at a minimum, the names, addresses, and telephone numbers of the five alternative suppliers. If there are fewer than five other such suppliers at the time of the referral, the physician must list all of the other suppliers of the referred service within a 25-mile radius of the physician's office.

The new disclosure requirement applies to all services furnished on or after January 1, 2011. Providers of imaging services that rely on the in-office ancillary services exception should begin preparing for this new disclosure requirement immediately. Providers should gather the names, addresses, and telephone numbers of other imaging providers in their area, and draft a form disclosure document to provide to patients.

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Physician-Owned Hospital Exception

PPACA significantly curtailed the physician-owned hospital exception to Stark. Only hospitals that have physician owners and provider agreements in place by December 31, 2010 are grandfathered and may take advantage of the exception. Such grandfathered hospitals, however, face many new restrictions. For example, the percentage of physician ownership of the hospital may not increase beyond the percentage in place on March 23, 2010. A grandfathered hospital also may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010. Finally, a grandfathered hospital faces new disclosure and patient safety requirements and prohibitions on offering investments to physicians on terms more favorable than those offered to non-physicians.

The final regulation clarifies many of the law's provisions. For example, under the final regulation, a physician owned hospital can qualify for the exception if it obtains its provider agreement after December 31, 2010 so long as the provider agreement's effective date is on or before December 31, 2010. The final rule also explains that transfers of physician ownership are permissible as long as the percentage of physician ownership does not increase above the percentage in place on March 23, 2010. A grandfathered hospital may decrease or increase the number of physician owners, or replace physician owners, as long as the aggregate percentage of physician ownership does not increase beyond the March 23rd percentage.

Finally, the final rule holds that a hospital with no physician owners as of March 23, 2010 may never qualify for the physician-owned hospital exception. PPACA was unclear on this point because it restricted the percentage of physician ownership to that in place on March 23, 2010 but also provided that a physician-owned hospital would be grandfathered if it had physician owners and a participation agreement in place by December 31, 2010. CMS interpreted the statute to provide that a hospital without physician owners on March 23, 2010 could not satisfy the exception by adding physician ownership between March 23 and December 31. In short, CMS found the March 23rd rule to be controlling.

Physician-owned hospitals should carefully review these final regulations and the law to determine how the additional restrictions will affect their current and planned operations.

We would be pleased to discuss the impact of this matter on your organization. Feel free to contact any member of the Bryan Cave [Life Sciences and Health Care](#) team.