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MMA-Clarifications to Certain Exceptions to Medicare Limits on Physician Referrals

Provider Types Affected

Physicians and specialty hospitals.

Provider Action Needed

Be sure to understand these new rules surrounding physician self-referral ("Stark") prohibition as a result of changes in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

GENERAL INFORMATION

A. Background: Under section 1877 of the Social Security Act (42 U.S.C. §1395nn), a physician cannot refer a Medicare patient for certain designated health services (DHS) to an entity with which the physician (or an immediate family member of the physician) has a financial relationship unless an exception applies. Section 1877 also prohibits the DHS entity from submitting claims to Medicare, the beneficiary, or any other entity for DHS that are furnished as a result of a prohibited referral.

The following services are DHS:

- Clinical laboratory services
- Radiology and certain other imaging services (including MRIs, CT scans and ultrasound)
- Radiation therapy services and supplies
- Durable medical equipment and supplies
- Orthotics, prosthetics, and prosthetic devices
- Parenteral and enteral nutrients, equipment and supplies
- Physical therapy, occupational therapy, and speech-language pathology services
- Outpatient prescription drugs
- Home health services and supplies
- Inpatient and outpatient hospital services.

A "financial relationship" includes both ownership/investment interests and compensation arrangements (e.g., contractual arrangements). The statute enumerates various exceptions, including exceptions for

physician ownership or investment interests in hospitals and rural providers. Violations of the statute are punishable by the following: denial of payment for all DHS claims; refund of amounts collected for DHS claims; and civil money penalties for knowing violations of the prohibition. Applicable regulations are published at 42 C.F.R. Part 411, Subpart J.

B. Policy: The MMA, also known as Public Law 108-173, altered the hospital and rural provider ownership exceptions to the physician self-referral prohibition. Prior to MMA, the “whole hospital” exception allowed physicians to refer Medicare patients to a hospital in which they had ownership/investment interests, as long as the physicians were authorized to perform services at the hospital and their ownership or investment interests were in the hospital itself and not a subdivision of the hospital.

Section 507 of MMA added an additional criterion to the whole hospital exception, specifying that for the 18-month period beginning on December 8, 2003 and ending on June 8, 2005, physician ownership and investment interests in “specialty hospitals” would not qualify for the whole hospital exception. Section 507 further specified that, for the same 18-month period, the exception for physician ownership or investment interests in rural providers would not apply in the case of specialty hospitals located in a rural area. **In other words, for this 18-month period only, a physician may not refer a patient to a hospital in which he/she has an ownership or investment interest if the hospital is a specialty hospital, even if the specialty hospital is in a rural area.**

Definition of a Specialty Hospital

For the purposes of these modifications to the physician self-referral prohibition exceptions only, a “specialty hospital” is defined as a hospital in one of the 50 States or the District of Columbia that is primarily or exclusively engaged in the care and treatment of one of the following:

- Patients with a cardiac condition,
- Patients with an orthopedic condition,
- Patients receiving a surgical procedure, or
- Patients receiving any other specialized category of services that CMS designates.

CMS is not designating at this time any additional specialized services that would cause an institution to be considered a specialty hospital within the meaning of section 507 of MMA.

Certain hospitals that offer specialized services are not “specialty hospitals” for purposes of section 507 of MMA. Physician investment in and referrals to the following types of hospitals are **permitted**:

- Psychiatric hospitals
- Rehabilitation hospitals
- Children’s hospitals
- Long-term care hospitals
- Certain cancer hospitals
- Existing specialty hospitals that satisfy the grandfathering provision in section 507 of MMA (“grandfathered specialty hospitals”).

Grandfathered Specialty Hospitals

A grandfathered specialty hospital is one that the CMS central office determines was in operation or under development as of November 18, 2003 and for which:

- (i) the number of physician investors has not increased since that date;
- (ii) the specialized services furnished by the hospital have not changed since that date; and
- (iii) any increase in the number of beds has occurred only on the main campus of the hospital and does not exceed the greater of 5 beds or 50 percent of the beds in the hospital as of that date.

A physician may invest in and refer to a grandfathered hospital. However, an existing specialty hospital cannot continue to be grandfathered if, after November 18, 2003, the number of physician investors or the type of specialized services it offers has changed, or if the hospital's bed size has increased beyond the 5-bed/50 percent threshold. Consequently, its physician investors cannot refer to the hospital and the hospital cannot submit claims pursuant to any prohibited referrals for the remainder of 18-month period ending on June 8, 2005. In determining whether a specialty hospital was "under development" as of November 18, 2003, the MMA directs CMS to consider whether the following had occurred as of that date:

- Architectural plans were completed;
- Funding was received;
- Zoning requirements were met; and
- All necessary approvals from State agencies were received.

In addition, CMS may consider any other evidence that CMS believes would indicate whether a hospital is under development as of November 18, 2003. If CMS determines that an entity was not under development as of November 18, 2003, it is not a grandfathered specialty hospital. Consequently, physician investors in that hospital may not refer to the hospital until June 8, 2005, and the hospital may not submit any claims for items or services rendered pursuant to a prohibited referral.

Grandfathering Determinations

Interested parties may submit to the CMS central office written requests for a determination that their specialty hospital was under development as of November 18, 2003 (a "grandfathering determination"). Existing specialty hospitals that had a provider agreement in effect as of November 18, 2003 do not need to request a grandfathering determination; the provider agreement will constitute this determination.

Grandfathering determination requests should include the following:

- A discussion establishing why the specialty hospital should be considered in operation before or under development as of November 18, 2003;
- Relevant supporting documentation;
- Contact information for an individual with whom CMS can discuss the request; and
- A certification that the information contained in the request and supporting documentation is true and correct and constitutes a complete description of the facts regarding the matter for which a determination is sought.

Upon receiving and reviewing the request, CMS may contact the requestor for additional information. Grandfathering determination requests may be mailed to:

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: Advisory Opinions
P.O. Box 26505
Baltimore, MD 21207

CMS contractors (for example, intermediaries and carriers) are not authorized to provide guidance on matters relating to the physician self-referral law or the application of the exclusion, civil monetary penalty, or criminal authorities under sections 1128, 1128A, or 1128B of the Social Security Act (including the anti-kickback statute).

Inquiries regarding the physician self-referral law should be directed to:

Joanne Sinsheimer
Division of Technical Payment Policy, CMS
(410) 786-4620

Inquiries concerning the application of the exclusion, civil monetary penalty, or criminal authorities under sections 1128, 1128A, or 1128B of the Social Security Act (including the anti-kickback statute) should be directed to the:

Office of Counsel to the Inspector General
Industry Guidance Branch
(202) 619-0335

Related Information

If you need further clarification, background, details or just want to see the original change request implementing the 18-month additional criteria, please refer to the original Change Request # 3036. This may be found at:

http://www.cms.hhs.gov/manuals/transmittals/comm_date_dsc.asp.

Once at that page, scroll down the CR Number column to CR 3036 and click on the file for that CR.