
CMS Manual System

Pub. 100-20 One-Time Notification

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 62

Date: MARCH 19, 2004

CHANGE REQUEST 3036

I. SUMMARY OF CHANGES: This one-time notification describes recent statutory changes regarding two ownership exceptions to the physician self-referral prohibition, §1877 of the Social Security Act (42 U.S.C.A. 1395nn). The changes were enacted by §507 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

NEW/REVISED MATERIAL - EFFECTIVE DATE: December 8, 2003

***IMPLEMENTATION DATE: April 2, 2004**

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)

(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
	N/A

***III. FUNDING:**

These instructions should be implemented within your current operating budget.

IV. ATTACHMENTS:

	Business Requirements
	Manual Instruction
	Confidential Requirements
X	One-Time Notification
	Recurring Update Notification

***Medicare contractors only**

One-Time Notification

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SUBJECT: Physician Self-Referral Prohibition; 18-Month Moratorium on Physician Investment in Specialty Hospitals

I. 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; and inpatient and outpatient hospital services. A “financial relationship” includes both ownership/investment interests and compensation arrangements (for example, 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 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA 2003)(Public Law 108-173) altered the hospital and rural provider ownership exceptions to the physician self-referral prohibition. Prior to MMA 2003, 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 2003 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.*

1. 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 we designate.

We are 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; and
- Existing specialty hospitals that satisfy the grandfather provision in Section 507 of MMA (“grandfathered specialty hospitals”).

2. 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 has 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 the 18-month period ending on June 8, 2005.

In determining whether a specialty hospital was “under development” as of November 18, 2003, section 507 of MMA directs us to consider whether the following had occurred as of that date:

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

We recognize that, in some cases, it may not have been feasible to complete all four of these steps. Thus, while all of the factors will be considered, we expect to make case-by-case determinations. In addition, we may consider any other evidence that we believe would indicate whether a hospital is under development as of November 18, 2003. If we determine 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.

3. Specialty Hospital Advisory Opinions

To obtain a determination regarding whether a specialty hospital was under development as of November 18, 2003, an interested party may submit to the CMS central office a written advisory opinion request. Existing specialty hospitals that had a provider agreement in effect as of November 18, 2003 do not need to request an advisory opinion; the provider agreement will constitute the determination that the specialty hospital was in operation before November 18, 2003.

The procedures for requesting an advisory opinion are set forth in our regulations at 42 CFR §§411.370 - 411.389. CMS will make every effort to expedite the issuance of specialty hospital advisory opinions. Consistent with the requirements of 42 CFR §411.372(b), specialty hospital advisory opinion 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 the advisory opinion is sought.

Upon receiving and reviewing the request, CMS may contact the requestor for additional information. If an entity receives an unfavorable determination about whether it was a specialty hospital under development before November 18, 2003, it may ask the CMS Administrator to rescind or revoke the advisory opinion. Specialty hospital advisory opinion 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 expects it will be able to process most determinations within 60 days of receiving complete information.

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, at (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, at (202) 619-0335.

- C. **Provider Education:** A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established “medlearn matters” listserv. Contractors shall post this article, or a direct link to this article, on their website and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin.

II. BUSINESS REQUIREMENTS

“Shall” denotes a mandatory requirement

“Should” denotes an optional requirement

Requirement #	Requirements	Responsibility
3060.1	<i>The contractors shall complete the tasks in the provider education section of this one time only notification.</i>	Carriers Intermediaries

III. SUPPORTING INFORMATION & POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions:

<i>X-Ref Requirement #</i>	Instructions
	None.

B. Design Considerations:

<i>X-Ref Requirement #</i>	<i>Recommendation for Medicare System Requirements</i>
	None.

C. **Interfaces:** None.

D. **Contractor Financial Reporting /Workload Impact:** The only work required is the provider education described above.

E. **Dependencies:** None

F. **Testing Considerations:** None.

IV. SCHEDULE, CONTACTS, AND FUNDING

<p>Effective Date: December 8, 2003</p> <p>Implementation Date: April 2, 2004</p> <p>Pre-Implementation Contact(s): Joanne Sinsheimer (410) 786-4620.</p> <p>Post-Implementation Contact(s): Joanne Sinsheimer (410) 786-4620.</p>	<p>These instructions should be implemented within your current operating budget.</p>
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