

Key Changes and New Interpretations Involving the Phase III Regulations

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Highlights of Important Changes Involving Several Exceptions and the New “Stand in the Shoes” Doctrine

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This article discusses certain aspects of the final Phase III regulations promulgated by the Department of Health and Human Services (HHS) on September 5, 2007.¹ The Phase III regulations amended HHS’ prior promulgated regulations regarding the legislation commonly known as Stark II, the physician self-referral prohibition in Section 1877 of the Social Security Act.²

Although the Phase III regulations and preamble provided a multitude of changes to the rules attendant to Stark II and new interpretations of the Centers for Medicare & Medicaid Services (CMS) of such rules, this article focuses on the changes to, and CMS’ new interpretations of, the following: (i) the physician recruitment exception; (ii) the rental of office space exception; (iii) the rental of equipment exception; and (iv) the personal service arrangements exception. Additionally, this article discusses the new “stand in the shoes” doctrine promulgated in the Phase III regulations.

By way of background, the legislation commonly known as Stark I was initially enacted in 1989 to prohibit referrals of Medicare patients for clinical laboratory services by physicians with financial relationships to such laboratories. In 1995, the scope of Stark II³ was expanded to include additional types of services and, indirectly, Medicaid referrals.

Stark II defines these “designated health services” as⁴: (i) clinical laboratory services; (ii) physical therapy services; (iii) occupational therapy services; (iv) radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services;

(v) radiation therapy services and supplies; (vi) durable medical equipment and supplies; (vii) parenteral and enteral nutrients, equipment, and supplies; (viii) prosthetics, orthotics, and prosthetic devices and supplies; (ix) home health services; (x) outpatient prescription drugs; and (xi) inpatient and outpatient hospital services (collectively, designated health services, or DHS).

If a physician or a member of the physician's immediate family has a "financial relationship" (hereinafter defined) with a health care entity, then the physician may not make a referral to that entity for the furnishing of DHS under the Medicare and Medicaid programs, unless an exception applies.⁵ An entity that renders any DHS based upon a referral from a physician with a "financial relationship" with the entity may not bill for the service under Medicare and Medicaid, unless an exception applies.⁶

There are two kinds of "financial relationships" under Stark II:⁷ (i) ownership or investment interests; and (ii) compensation arrangements. Ownership and investment interests can be through debt, equity, or other means and can be indirect. Compensation arrangements can potentially include any remuneration to a physician. Accordingly, Stark II addresses very broad categories of activity.

Sanctions for violations of Stark II can include denial of payments, refund requirements, civil money penalties of up to \$15,000 for each service rendered, and exclusion from the Medicare and Medicaid programs.⁸ Additional civil penalties may be triggered of up to \$100,000 by schemes designed to circumvent the statute⁹ or of \$10,000 per day by failure to meet certain reporting requirements.¹⁰

On January 4, 2001, the Department of Health and Human Services promulgated Phase I regulations.¹¹ Most of the provisions of the Phase I regulations became effective on January 4, 2002, except for Section 424.22(d), which became effective April 6, 2001.¹² Thereafter, HHS promulgated the

Phase II regulations on March 26, 2004.¹³ The Phase II regulations set forth the self-referral prohibition and applicable definitions, interpreted various exceptions of the self-referral prohibition set forth in the Stark II legislation, and created additional regulatory exceptions for arrangements that do not pose a risk of program or patient abuse.¹⁴ The Phase II regulations became effective on July 26, 2004. The Phase III regulations, certain aspects of which are the focus of this article, were then promulgated by HHS on September 5, 2007.¹⁵ Most of the provisions of the Phase III regulations become effective December 4, 2007.¹⁶

Stark II, as supplemented by the Phase I, Phase II, and Phase III regulations, contains numerous exceptions to Stark II's prohibitions, including but not limited to: (i) the physician recruitment exception; (ii) the rental of office space exception; (iii) the rental of equipment exception; and (iv) the personal service arrangements exception. Changes to such exceptions and CMS' interpretations thereto in the Phase III regulations' preamble are discussed below. Additionally, discussed below is the new "stand in the shoes" doctrine set forth in the Phase III regulations.

PHYSICIAN RECRUITMENT EXCEPTION¹⁷

Section 1877(e)(5) of the Social Security Act¹⁸ states that the physician recruitment exception applies "[i]n the case of remuneration which is provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the medical staff of the hospital if: (i) the physician is not required to refer patients to the hospital; (ii) the amount of the remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referral by the referring physician; and (iii) the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse."

The Phase III regulations modified the Phase II regulations regarding the physician recruitment exception as follows:¹⁹

- (i) Allowing rural health clinics (in addition to hospitals and federally qualified health centers) to use this exception;
- (ii) Deeming the geographic area served by a hospital to be the area comprised of all of the contiguous zip codes from which the hospital's inpatients are drawn if the hospital draws fewer than 75 percent of its inpatients from contiguous zip codes;
- (iii) Allowing an alternative test to determine the "geographic area served by the hospital" for a hospital located in a rural area (*i.e.*, use of the lowest number of contiguous, or in some cases, noncontiguous, zip codes from which a rural hospital draws at least 90 percent of its inpatients);
- (iv) Allowing a more generous income guarantee in certain circumstances for a physician that a physician practice located in a rural area or health professional shortage area (HPSA) recruits to replace a deceased, retiring, or relocating physician;
- (v) Allowing group practices to impose certain practice restrictions on a recruited physician;
- (vi) Allowing rural hospitals to recruit physicians into an area outside of the hospital's geographic area if the Secretary of HHS determines through an advisory opinion that the area has a demonstrated need for the recruited physician;
- (vii) Exempting from the relocation requirement a physician who, for the two years immediately prior to the recruitment arrangement, was employed on a full-time basis by a federal or state bureau of prisons (or similar entity operating correctional facilities), the Department of Defense or Department of Veterans Affairs, or facilities of the Indian Health Service, as long as the physician did not maintain a separate private practice in addition to such full-time employment;
- (viii) Exempting from the relocation requirement those physicians whom the Secretary of HHS has deemed in an advisory opinion not to have an established medical practice comprised of a significant number of patients of the recruiting hospital;
- (ix) Clarifying that a physician must relocate his or her practice from outside the geographic service area to a location inside the service area and either: (a) move his or her medical practice at least 25 miles; or (b) have a new medical practice that derives at least 75 percent of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior medical practice site, during the preceding three years, measured on an annual basis (fiscal or calendar year); and
- (x) Clarifying that an income guarantee made by a hospital to a recruited physician who joins a physician practice applies to any type of income guarantee.

General Conditions

The Phase III regulations reflect that the physician recruitment exception applies to remuneration provided by a hospital to recruit a physician that is paid directly to the physician and is intended to induce the physician to "relocate his or her medical practice" (as hereinafter defined) to the "geographic area served by the hospital" (as hereinafter defined) in order to become a member of the hospital's medical staff if all of the following conditions are met:

- The arrangement is set out in writing and signed by both the hospital and physician.
- The arrangement is not conditioned on the physician's referral of patients to the hospital.
- The hospital does not determine (directly or indirectly) the amount of the remuneration to the physician based on the volume or value of any actual or anticipated referrals by the physician or other business generated by the parties. (For

