

## CMS Press Release Announcing The Imminent Publication of New Stark Regulations

On March 25, 2004, the CMS issued a press release announcing the imminent publication of interim final regulations addressing physician referrals to entities with which they have a financial relationship. The physician self-referral law, commonly known as the "Stark Law" prohibits a physician from referring Medicare and Medicaid patients for certain designated health services to entities with which the physician (or a member of the physician's immediate family) has a financial relationship, unless an exception applies. The law also prohibits an entity from billing for services provided as a result of a prohibited referral.

The designated health services initially covered by the Stark Law included only clinical laboratory services. The law was subsequently expanded to also include physical therapy services; occupational therapy services; radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. Under the Stark Law, a financial relationship can be either a compensation arrangement or an ownership or investment interest, direct or indirect.

Final regulations applicable only to physician referrals for clinical laboratory services were published in August 1995. A proposed rule applicable to physician referrals for all designated health services was published in January 1998. In January, 2001, CMS published the "Phase I" final rule, which finalized a significant portion of the 1998 proposed rule. The Phase I final rule defined many of the terms in the Stark Law, interpreted some of the major statutory exceptions, and created a number of new regulatory exceptions.

The regulations being published now are the "Phase II" final rules. These regulations respond to comments CMS received on the first phase of the regulations, cover the remaining statutory exceptions not covered in the first phase, and create several new regulatory exceptions for nonabusive financial relationships. The new regulations will be published in the Federal Register on Friday, March 26, 2004 and will be effective on July 24, 2004. According to the CMS, the new regulations generally conform to existing coverage and payment rules; protect beneficiary access to care; and establishes bright-line rules and administrative simplicity where possible.

In responding to comments on the first phase of the regulation, CMS stated that it attempted to protect legitimate arrangements involving certain specialty groups that primarily furnish oncology and radiology services. In addition, CMS stated that it revised the definition of compensation that is "set in advance" to permit certain common percentage compensation arrangements; made the academic medical centers exception more flexible; expanded the medical staff incidental benefits exception to include facilities other than hospitals; and expanded the exception for certain dialysis-related drugs to include more drugs used in connection with dialysis treatment.

According to the CMS, the statutory exceptions addressed in this second phase include those for physician investment interests in publicly traded securities and mutual funds and physician ownership of rural providers and hospitals. The new regulations revise the hospital ownership exception to reflect the new 18-month moratorium on physician ownership of specialty hospitals, which was recently enacted in section 507 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA 2003).

The new regulations also interpret a number of statutory exceptions for compensation arrangements involving physicians, including the exceptions for space and equipment rentals, employment relationships, personal services arrangements, and physician recruitment. Regarding the employment exception, CMS eliminated a proposed restriction on productivity bonuses, making it clear that physician employees may be paid bonuses based on their personal productivity (but not referrals for ancillary services).

The new regulations contain a new provision that deems certain hourly payments to physicians to be consistent with fair market value, a key requirement for most compensation arrangement exceptions. CMS also expanded the recruitment exception to apply to physician recruitment conducted by federally qualified health centers (FQHCs).

This second phase of the regulations also creates exceptions for Medicaid managed care plans; professional courtesy arrangements; certain inadvertent and temporary lapses in compliance with an existing exception; charitable contributions by physicians to entities that furnish designated health services; payments made by a hospital or FQHC to a physician to retain the physician's needed medical practice in a health professional shortage area; and technology items or services furnished to physicians to enable their participation in a community-wide health information system.

The exception for community wide health information systems is related to the Department's efforts to encourage provider use of electronic health records, which are fundamental to the National Health Information Infrastructure. The exception involves certain items or information technology services provided by an entity to a physician that allow access to patient electronic health care records, general health information, medical alerts, and related information for patients served by community providers. The CMS claims that this exception for community-wide health information systems will have very positive advantages for American health care by enhancing the country's movement toward a national health information infrastructure that will serve consumers, patients, health care providers and public health professionals.

Local community health information infrastructures, with privacy and security protections, will make it easier for health care providers to share relevant patient information and for public health professionals to identify emerging public health threats, according to CMS. Although the Stark Law requires entities that provide designated health services to report information concerning their financial relationships with physicians, the new regulations specify that such information need not be reported on a regular or periodic basis. Instead, the new regulations require providers to make the information available only upon the Department's request.

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