Stark final rule part II released; lithotripsy contracts may need to meet an exception

by Robin Hudson

On March 26, the Centers for Medicare & Medicaid Services (CMS) released part two of its final rule interpreting the physician self-referral, or Stark, law. The first part of the final rule was released in January 2001; the rules address different aspects of the law. The new regulations go into effect on July 26, 2004, and there is an opportunity for public comment until June 24. In the new rule, CMS attempts to provide more bright-line guidance for these extremely complex regulations and to simplify the requirements where possible.

Importantly, this final rule includes CMS's interpretation of the judge's decision in the 2002 lawsuit by the American Lithotripsy Society (ALS) and the Urology Society of America (USA), which argued that lithotripsy should not be considered a designated health service (DHS) for purposes of the Stark law.

Basics

The physician self-referral law prohibits a physician from referring Medicare and Medicaid patients for DHSs to health care businesses with which the physician (or an immediate family member) has a financial relationship, unless an exception applies. The law also prohibits the health care business from filing claims with Medicare for those referred services, unless an exception applies. Financial relationships can be direct or indirect and include ownership interests, investment interests and compensation arrangements.

"The new regulations will protect Medicare beneficiaries from potentially abusive referrals, while accommodating legitimate business and financial arrangements, including those that enhance the emerging national health information infrastructure," said CMS.

Lithotripsy

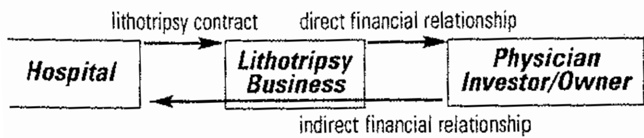
The Stark law's effect on arrangements between lithotripsy ventures and hospitals has been the focal point of concern for urologists since release of the Stark proposed rule back in 1998. Under Medicare billing rules, lithotripsy services must be billed through a hospital outpatient department. And, because hospital outpatient services are DHSs under the Stark law, lithotripsy was originally considered by CMS to be a DHS. However, in 2002, ALS and USA were successful in a court challenge that lithotripsy should not be considered a DHS. Thus, CMS agrees in the final rule that they will not consider lithotripsy an inpatient or outpatient service for purposes of the Stark law.

However, CMS points out that contractual arrangements between hospitals and lithotripsy ventures still create a financial relationship (usually an indirect compensation arrangement) between the physician and the hospital (if the physician owns or invests in the lithotripsy venture) under the Stark law. For lithotripsy, once it has been determined that a financial relationship exists between the referring physician and the hospital, the next question to ask is whether the physician refers patients to the hospital for *any* DHS.

Even though lithotripsy is no longer considered a DHS, if a financial relationship between the physician and the hospital has been established through the lithotripsy venture, and that physician refers patients to the hospital for any DHS, lithotripsy contracts still must comply with an exception. This is because the law prohibits referrals to an entity with which the physician has a financial relationship–unless an exception applies.

Conversely, if the physician refers patients to the hospital for lithotripsy but does not refer patients to the hospital for any other DHSs, the lithotripsy contract need not comply with a stark exception.

Example of indirect compensation arrangement for lithotripsy:



DHSs are: clinical lab services, physical therapy services, occupational therapy services, radiology 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.

Other changes in the final reg

Although the Stark law has some built-in statutory exceptions to the law, it also allows CMS to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Based on comments to the first final rule, CMS has created several new regulatory exceptions for what they consider to be nonabusive financial relationships, including:

- For arrangements that have unavoidably and temporarily fallen out of compliance with other exceptions
- For some intra-family referrals that meet specific conditions (two-physician families)
- For community-wide health information systems

CMS also slightly revised existing exceptions, including the in-office ancillary services exception, which was tweaked to accommodate physicians who provide DHS as a core part of their medical practice, such as radiologists and oncologists.

Specialty hospitals

The Stark law includes an exception for physicians who have ownership or investment interests in a whole hospital (versus a subdivision of the hospital). However, last December, Congress put a moratorium on physician investment in and referrals to certain specialty hospitals. Thus, CMS had to adjust the language in the Stark regulations so that

See Stark p. 8

[f]rom p. 3

[own]ership and investment interests in [sp]ecialty hospitals would not qualify for [t]he whole hospital exception. CMS recently announced details of its plan to implement the moratorium on physician investment, which lasts from December 8, 2003 to June 8, 2005. Under the moratorium, physicians may not refer a patient to a specialty hospital in which they have an ownership or investment interest, and the hospital may not bill Medicare or any other entity for services provided as a result of a prohibited referral.

The moratorium applies to hospitals that are primarily or exclusively engaged in the care and treatment of patients with cardiac or orthopedic conditions, patients receiving surgical procedures and patients receiving any other specialized type of services that CMS may designate. Congress also excluded from the moratorium hospitals that were in operation before or under development as of November 18, 2003.

Stay tuned

The AUA is still in the process of analyzing the new regulations and their effect on urologists who have a financial interest in a lithotripsy company and also their effect on other issues of importance to urologists, such as distribution of profits for DHSs such as outpatient chemotherapy drugs. Stay tuned for a legal analysis of the regulation as well as information and talking points for submitting your own comments to the Medicare agency. Meanwhile, it is important to seek your own legal counsel to assure that your lithotripsy contracts meet any necessary exceptions and that you are taking full advantage of the fair market value interpretations in the regulations. ■