

Thirteen Things Providers Should Know About Stark Law and Physician Ownership Changes Under Health Reform

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One dramatic and early impact of health care reform upon providers comes in the form of changes to the Stark law's "whole hospital" exception, which currently permits physicians to refer to hospitals in which they hold an ownership interest. Amendments to the Stark law included in Section 6001 of The Patient Protection and Affordable Care Act (PPACA), as amended by the Health Care and Education Reconciliation Act of 2010, will limit future physician ownership or investment in hospitals. Under the new law, the whole hospital exception will only apply to protect physician ownership in hospitals that are "grandfathered" – that is, those that have physician ownership and an effective Medicare provider number before December 31, 2010. In its Hospital Outpatient Prospective Payment System proposed rule released August 3, 2010, CMS included its proposals for implementing the changes. 75 Fed. Reg. 46170, 46433, August 3, 2010. The law and proposed regulations strictly limit the expansion of space or services of any "grandfathered" hospitals and impose new requirements for transparency and disclosure.

1 The Stark Law Prohibition on Referrals. Section 1877 of the Social Security Act (SSA), also known as the "Stark law," prohibits a physician from making referrals for certain "designated health services" (DHS) payable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship in the form of ownership or compensation, unless an exception applies. Inpatient and outpatient hospital services are DHS.

Since its passage, the Stark law and regulations have included exceptions related to ownership interests including

an exception for ownership in a whole hospital, that is, physicians may refer patients to a hospital where they have an ownership interest in the hospital itself and not merely in a subdivision of the hospital.

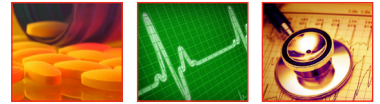
2 Prior Efforts to Limit the Whole Hospital Exception. As early as 2003, Congress considered limiting the scope of the whole hospital exception and in particular focused on specialty hospitals that were often perceived as skimming the cream of high-margin surgeries from the general acute care hospitals.

In 2003, Congress imposed an 18-month moratorium on physician ownership in specialty hospitals. For those months, it was a violation of the Stark law for a physician to refer a Medicare patient to any specialty hospital in which he had an ownership interest. As passed by Congress, the moratorium did not prevent physicians from building or investing in specialty hospitals. Later, however, CMS itself suspended the enrollment of new physician-owned specialty hospitals.

In 2006, both the referral moratorium and the enrollment suspension were concluded. Physicians resumed referring Medicare patients to specialty hospitals in which they have ownership or investment interests that satisfied the whole hospital exception and newly-established physician-owned hospitals could enroll in Medicare.

From time to time, efforts to prohibit or limit physician ownership and investment in specialty hospitals have been resurrected and Congress has considered proposals to do away with the Stark law exception for all hospitals. Under the PPACA, that prohibition has arrived.

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3 Changes to the Whole Hospital Ownership Exception. The PPACA has all but eliminated the whole hospital exception, except for grandfathered institutions. Under the revised Stark law, a hospital which does not meet the exception will not be able to accept Medicare referrals from any physician owner or person related to the physician owner. In fact, even hospitals with physician owners that have been eligible for the whole hospital exception in the past may lose the exemption if, in a sale or other change of ownership, the post-transaction level of physician ownership exceeds the percentage of such ownership on March 23, 2010.

These changes will, in essence, discourage if not preclude the construction of new physician-owned hospitals and will restrict the transfer of existing physician interests in grandfathered hospitals.

The only physician-owned hospitals that will meet the Stark law exception going forward are those who meet the following criteria. A hospital must:

- Have physician-owners or investors and a provider agreement in effect no later than December 31, 2010;
- Not expand facility capacity beyond the number of operating rooms, procedure rooms, and beds for which the hospital was licensed as of March 23, 2010;
- Comply with certain reporting and disclosure requirements;
- Comply with certain requirements designed to ensure that all ownership and investment interests in the hospital are bona fide;
- Inform patients before admission if the hospital does not have a physician available on the premises during all hours and receive a signed acknowledgment that the patient understands this fact; and,
- May not have been converted from an ambulatory surgical center on or after March 23, 2010.

4 Important Deadlines. To satisfy the grandfathering provisions of the whole hospital exception, the proposed

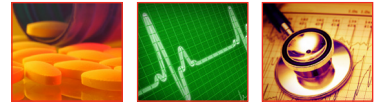
rule requires a physician-owned hospital to meet certain new requirements described in the PPACA no later than September 23, 2011. CMS's proposed regulations indicate that the deadline for compliance with all provisions that do not contain an explicit deadline is September 23, 2011; that is, 18 months after the date of enactment. However, as is discussed below, the law has several significant date-based thresholds that become effective much earlier. CMS has stated that failure to satisfy earlier deadlines will preclude use of the revised exceptions after the earlier deadline has passed.

5 Grandfathered Hospitals. The law provides for a grandfathering of certain existing physician-owned hospitals. To be eligible for the whole hospital exception a hospital must have physician ownership or investment on or before December 31, 2010, and must also have a Medicare provider agreement in effect on that date.

This is a challenge for providers with new hospital construction that was planned prior to the passage of the PPACA and is currently under construction. Those facilities will be pressed to get provider agreements in place by December 31, 2010. Notably, CMS recently amended 42 C.F.R. § 489.13(b) to provide that the effective date of a provider agreement may not be earlier than the latest of the dates on which each applicable federal requirement is determined to be met, including the final approval of the enrollment application or the survey. 75 Fed. Reg. 50400, 50041, August 16, 2010.

In cases where the CMS contractor finds that the prospective provider's or supplier's compliance with enrollment requirements did not occur until ...the accreditation survey and accreditation decision take(s) place, it is our policy, to make the effective date of the provider agreement...the date when the enrollment requirements are considered to have been met. Specifically, the effective date would be the date that CMS determines...that the applicant is in compliance with all enrollment requirements and CMS is prepared to convey

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Medicare billing privileges to the provider or supplier. However, if there are still other Federal requirements that remain to be satisfied, such as submission of required civil rights compliance documentation the effective date would be the date when the last requirement has been satisfied, as determined by CMS.

Thus, any new provider should be focused on submitting enrollment information (Form 855) to the Medicare contractor and scheduling a survey as soon as possible. Failure to obtain a provider agreement that is effective on or before December 31, 2010, will cause the hospital to miss out on grandfathering and preclude use of the whole hospital exception on and after January 1, 2011.

6 Limitation on Expansion of Facility Capacity.

Even those physician-owned hospitals that qualify to be grandfathered will find that the exception comes with limitations. These hospitals are effectively frozen in time in two ways: by existing capacity and by percentage of physician ownership.

A grandfathered hospital will be limited to the physical plant – those operating rooms, procedure rooms, and beds – for which the hospital is licensed at any time on or after March 23, 2010. Here again, there was some confusion regarding deadlines because PPACA does not address the capacity issue for those hospitals enrolled between March 23, 2010 and December 31, 2010. CMS proposed that grandfathered hospitals be limited to the number of operating rooms, procedure rooms, and beds for which the hospital is licensed on March 23, 2010, or if the hospital did not have a provider agreement on that date, but does have an agreement in effect on December 31, 2010, the capacity will be ‘fixed’ on the effective date of such provider agreement.

The Act specifies that “the term ‘procedure rooms’ includes rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed, except such term shall not include emergency rooms or departments (exclusive of rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed).” Although PPACA would permit

CMS to include rooms where other services are performed, CMS’s proposed definition of procedure rooms limits the definition to the types of rooms specified in the statute. CMS solicited public comments on whether “procedure rooms” should include rooms where additional services, such as CT or PET scans, or other services, are performed.

7 Exception Process on Capacity to be Developed.

The Act gives the Secretary until January 1, 2012 to promulgate regulations and to implement an exception process that would permit hospitals to expand once every two years. Exceptions for expanding facility capacity will protect only those referrals made after the exception is granted. The increase will be limited to facilities on the main campus of the hospital.

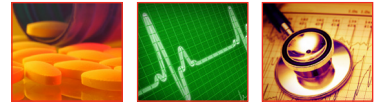
8 Limiting Physician Ownership Percentages.

Only bona fide ownership interests will be eligible for the whole hospital exception. Section 1877(i) (1)(d) of the SSA sets forth seven requirements related to ensuring bona fide investment in order for hospitals to qualify for the whole hospital exception.

Perhaps the most limiting of these requirements is that the percentage of the total value of the ownership or investment interests held in the hospital by physician-owners in the aggregate may not exceed the percentages of ownership in place on March 24, 2010. One source of confusion was how the December 31, 2010 deadline for having a provider agreement related to this earlier deadline for physician ownership. PPACA does not expressly address what happens between March 23 and December 31, and CMS has stated its position that the earlier deadline applies. That is, if a hospital has no physician ownership as of March 23, 2010, and later adds physician owners or investors, the hospital will not satisfy the whole hospital exception.

The effect of this provision would dictate that physicians could purchase shares only from other selling physicians (otherwise the aggregate percentage of physician ownership in the hospital would increase, which would cause all

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physicians' investment interests in the hospital to fall outside the exception and, accordingly, trigger the Stark law's prohibition on Medicare referrals and related claims). A hospital may reduce the number of physician owners or investors, provided that the percentage of the total value of physician ownership or investment interests, in the aggregate, remains the same or decreases.

It must be noted that under the proposed regulation, no distinction is made between referring and non-referring physicians. That is, it appears that all physician ownership – not just the shares of referring physician ownership – will be included in the ownership percentages. Prior to PPACA, a non-referring physician could own a hospital – or part of a hospital – without having any impact on other physicians under Stark so long as he did not refer to that hospital. As proposed, even a de minimus ownership interest (other than ownership in publicly-traded companies) held by a non-referring physician, if it pushes the physician ownership over the new threshold, could preclude all physician owners from referring to the hospital. Moreover, the ownership interests of relatives of owner-physicians will also be included under the proposed regulation. There is no provision made for grace periods to divest interests which undermine eligibility for the exception (such as if a referring physician or family member inherits an interest in a hospital or an owner becomes a physician after ownership is established.)

9 Bona Fide Interests. The remaining six indicia of bona fide investments are similar to those discussed in safe harbors to the anti-kickback safe harbors applicable to investment interests. For example:

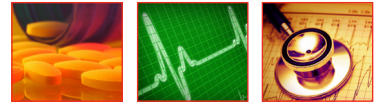
- A hospital may not limit physician ownership or investment to those making or influencing referrals to the hospital or otherwise generating business for the hospital.
- A hospital must not offer a physician the opportunity to purchase or lease any property under the control of the hospital on terms more favorable than those offered to an individual who is not a physician owner.

- A hospital must not directly or indirectly provide loans or financing for any investment in the hospital by a physician. The hospital must not directly or indirectly guarantee a loan, make a payment toward a loan, or otherwise subsidize a loan, for any individual group of physician owners that is related to acquiring any ownership interest in the hospital.
- Returns on investment must be distributed to each owner in the hospital in an amount that is directly proportional to the ownership or investment interest of such owner or investor in the hospital.
- Physician owners and investors must not receive, directly or indirectly, any guaranteed receipt of or right to purchase other business interests related to the hospital, including the purchase or lease of any property under the control of other owners or investors in the hospital or located near the premises of the hospital.

10 Transparency and Enforcement. Hospitals are required to provide an annual report to HHS on the identity of each physician owner and any other owners or investors of the hospital along with the nature and extent of those ownership and investment interests. CMS proposes that a hospital must require each *referring physician owner*, as a condition of continued medical staff membership or admitting privileges, to provide written disclosure of his or her ownership interest in the hospital to all patients the physician refers to the hospital. This notice must be provided in time for the patient to make a meaningful decision on the receipt of care.

The proposed regulations obligate the hospital to disclose on public websites or in any advertising the fact that the hospital is partially owned by physicians. The PPACA authorizes the Secretary to collect, publish, and update on an annual basis on the CMS web site (<http://www.cms.hhs.gov>) the physician and other ownership information submitted by hospitals.

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11 Patient Safety. Hospitals must have the capacity to provide assessment and initial treatment for patients and also to transfer such patients to hospitals with the capability to treat the patients involved. CMS says these patient safety requirements will apply to inpatients as well as outpatients. Section 1877(i)(1)(e) of the SSA requires a hospital that is owned by physicians to disclose to a patient before admission if it does not have a physician available on the premises to provide services during all hours that the hospital is providing services to such patient. Following this disclosure, the hospital must receive a signed acknowledgment of such fact from the patient.

12 Enforcement. The PPACA requires the Secretary to establish policies and procedures to ensure compliance with the requirements of the SSA, which may include unannounced site reviews of hospitals. Section 6001(b)(2) of the PPACA requires the Secretary, beginning not later than May 1, 2012, to conduct audits to determine if physician-owned hospitals are in compliance with the Stark law.

13 Implications of These Changes. According to some estimates, health reform's ban on physician-

owned hospitals has halted construction on over 30 facilities. According to Physician Hospitals of America, close to 40 physician-owned hospitals are either pushing ahead with construction or have transferred all physician ownership to non-physician ownership. At least one lawsuit has been filed seeking injunctive relief against the implementation of this section. We anticipate that further litigation will follow as the deadline approaches and investors face the loss of capital invested in projects that will no longer be eligible for Medicare reimbursement.

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