The Changing Landscape of Physicians' Self-Referral Regulation

Major Changes Expected to Stark Law, Physician Ownership of Hospitals

BY BART WALKER

After a year of relative peace and quiet on the physician self referral front, Congress, along with the Centers for Medicare & Medicaid Services (CMS), in the past couple of months have taken steps to swing the pendulum back in the direction of greater governmental restrictions on the ability of physicians to make self-referrals to certain entities in which they have an economic interest.

On July 12, 2007, CMS published a proposed rule containing certain major substantive changes to the Stark Law, which governs physician referrals to entities in which the physician has a financial interest. These changes, if enacted, would have a major impact on the provision of care and on the ability of physicians to refer to certain facilities. These changes are aimed at what CMS perceives as abuses or gaming of the system resulting in overall higher healthcare costs and higher payments to healthcare providers from the Medicare and Medicaid programs. In addition to the Stark Law changes, a bill was introduced on July 24 in the United States House of Representatives entitled "The Children's Health & Medicare Protection (CHAMP) Act." In addition to providing funds to states to implement universal coverage programs for children, the bill also includes a couple of key provisions that will have an immediate and substantial impact on physicians and their referral patterns.

Stark Law Changes

1. Prohibition on "Per Click" Leases.

Perhaps the single most important change in the proposed Stark Law revisions would be the effective prohibition of "per unit of service" or so-called "per click" arrangements in space and equipment leases. In a typical situation, a physician or physician-owned entity would own a MRI machine, for example, and then lease that MRI machine on a peruse or per-click basis to healthcare providers who are using the MRI machine. In this situation, the physician owners of the MRI machine would be encouraged to make referrals to the hospital or to the physicians who are leasing the MRI machine in order to increase the number of uses or clicks on that machine and thus in turn increase the lease payments back to the physicians. This type of referral pattern is viewed by CMS as being particularly susceptible to abuse. One other structure that has been popularized recently is the lease by physicians

of imaging equipment on a per-click rental basis. Here, the physician would self-refer patients to utilize the diagnostic imaging equipment and then as a result, pay only a flat per-click fee to the owner of the imaging equipment. The result is that the profitability for the physician of the professional fee component is tied directly to the utilization of the piece of equipment.

2. "Under Arrangements" Restrictions. The other key change proposed by the new Stark Law regulations would be an effective ban on many types of "under arrangements", structures that are sometimes referred to as "contractual joint ventures." These are common where a physician-owned entity or a physician and hospital joint venture entity owns infrastructure (such as equipment, space or personnel) and then that entity provides the infrastructure to the hospital or other providers in the community on an "under arrangements" basis. The provider would then bill the professional fee component to Medicare, Medicaid or other third party payors. If the provider is a hospital, the professional fees are sometimes billed to payors at the hospital reimbursement rate (which is often higher than the physician or outpatient facility rate). The hospital then pays a lease rate to the entity providing the infrastructure, space or personnel that is used in providing the services to the patient. This situation has become more common recently in imaging joint ventures which would otherwise not be permissible if structured as a true joint venture under the Stark Law (i.e., physician ownership in stand-alone imaging centers outside of their offices is not generally allowed). In a typical imaging venture that CMS views as an abuse, the hospital (or other third party) and physicians would create a joint venture entity to own the expensive imaging equipment, space and personnel and then that entity would provide these infrastructure services to the providers. The physicians would then be able to share in a portion of the proceeds by virtue of the lease payments paid by the hospital to the entity providing the equipment and space with which to provide the imaging services. If the rules are enacted as proposed, this could very well signal an end to most of the more recent kinds of under arrangement models that we have seen. If you are currently involved in an under arrangements deal or considering entering into one, you should be aware that these changes are on the horizon and may cause certain of these arrangements to be deemed impermissible.

3. Percentage Compensation. One of the touchstones of permissible compensation relationships in the self-referral area is the concept of "fair market value." In many of the Stark Law exceptions, such as the personal services exception, for example, the fees paid to physicians must be consistent with fair market value and set in advance. Up until now, fees based on a percentage of some number, whether it be revenue or case volume, have been generally permissible and considered "set in advance" in compliance with the currently available regulatory guidance. This change would prevent many pay for performance arrangements whereby physicians receive a percentage of revenue earned or percentage of costs savings achieved. It is expected that there would still be an exception for fees based on a percentage of revenues generated based on the physician's own performance of services.

4. In-Office Ancillary Services. The proposed rules would make certain changes to the in-office ancillary services exception to the Stark Law. Traditionally, under the in-office ancillary services exception to the Stark Law, physicians could offer certain services and bill Medicare or other insurers for the services performed in their own offices for which they otherwise could not bill payors if performed outside their offices. This has led to certain abuses whereby physicians would lease space or equipment in places that were not intended by Congress to constitute being "in" a physician's office. Although CMS expressed a willingness to crack down on these types of arrangements and the proliferation of services offered pursuant to the in-office ancillary services exception, it did not propose a specific set of rules to govern these relationships. These types of relationships are particularly common in independent diagnostic testing facilities, or IDTFs.

5. Anti Mark-Up Provisions. CMS has proposed that physicians would be prohibited from marking up the value of services they provide to Medicare from what it actually costs them to provide the services in certain circumstances. The area they are targeting here is the provision of diagnostic imaging services. The

perceived abuse is that a physician would lease or rent equipment or space to provide diagnostic services, for example, for \$50 per procedure, but according to the Medicare reimbursement schedule, the procedure itself would pay \$100. This would result in an additional profit to the physician of \$50 in this example in addition to the reimbursement amount. Again, here the abuse is one in which the financial relationship creates an incentive for self-referral and over-utilization of these services.

The CHAMP Act

The second piece of proposed regulatory changes is the Children's Health and Medicare Protection Act or the CHAMP Act, which was introduced in the House on July 24. In addition to providing states an allotment for provision of healthcare to children, the bill also includes a couple of very significant provisions which directly impact physicians, hospitals and healthcare providers. The first significant portion of this bill is rather than having a negative 10 percent physician reimbursement cut in 2008 and a 5 percent physician reimbursement cut in 2009, this bill would enact a 5 percent update to physician reimbursement in both 2008 and 2009. The downside for physicians is that while they would get a higher reimbursement rate as a result of this bill, the bill also contains a strict prohibition on the ability of physicians to refer to hospitals in which they have an ownership interest. This ongoing debate has been argued and fought for a number of years. Many of you will recall there was a moratorium on investment in physician-owned hospitals or "specialty hospitals" that lasted for several years and which recently expired in 2006. Development of physician owned hospitals has picked back up in the last year and a half as a result of the expiration of the moratorium but this bill would put in place certain serious restrictions on the ability to develop these hospitals.



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