

HEALTH CARE ISSUES

The Health Care Department at Murtha Cullina is pleased to provide clients and friends with information about topics of interest in the health care area.

If you have questions about the issues addressed in this newsletter, or any other matters involving health care legal issues, please feel free to contact the following attorneys:

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URGENT NOTICE TO HOSPITALS

DO A STARK COMPLIANCE AUDIT NOW: CMS WILL DEMAND DETAILS OF REPORTABLE FINANCIAL RELATIONSHIPS WITH PHYSICIANS, ENHANCED STARK ENFORCEMENT TO FOLLOW



Elizabeth Neuwirth

Now is the time to develop a list of all your hospital-physician relationships and audit to ensure they comply with the Stark exceptions. In September, CMS will begin electronically sending a Disclosure of Financial Relationship Report (“DFRR”) to 500 hospitals. Hospitals will be required to submit the completed DFRR to CMS within 45 days or face civil monetary penalties of up to \$10,000 for each day beyond the deadline established for disclosure. In theory, a hospital that fails to respond fully and truthfully to the DFRR may also subject itself to False Claims Act enforcement if CMS requires the DFRR to be certified by the hospital as a Medicare condition of participation.

The mandatory data collection initiative, which has elicited objections from some major hospital trade groups, is noteworthy because it appears to go well beyond what CMS was required to do by Congress. The Deficit Reduction Act instructed the agency to develop a plan to regulate physician investment in specialty hospitals. However, the DFRR will be sent to non-specialty hospitals as well. CMS has indicated it will eventually seek the same information from all Medicare-participating hospitals.

CMS clearly intends to use the DFRR process as a wake-up call to hospitals about the risks of non-compliance with the Stark requirements, violation of which carries the same penalties as failure to respond to the DFRR. CMS has previously expressed concern that hospitals are not putting their arrangements with physicians into written form or keeping them current, readily available upon demand by CMS or the OIG, and cross-referenced to show all financial relationships with physicians and their immediate families.

Stark II Phase II added a requirement that entities that furnish designated health services (“DHS”) keep records of their “reportable financial relationships” (“RFR’s”) and provide them within thirty (30) days upon request of CMS or the OIG. With very limited exceptions, an RFR is any ownership or investment interest or a compensation arrangement that exists between the entity that provides the DHS and a physician or immediate family member. The records must include the name and provider number of each physician who has, or who has an immediate family member who has, an RFR with the entity; the DHS furnished by the entity; and the nature and value of the RFR. Note that an “immediate family member” includes a spouse and the physician’s birth/adoptive/step-/in-law father, mother, child, or sibling.

Once everything is in writing, current, cross-referenced and readily available, hospitals need to check the content of the agreements, because they face even greater danger from hospital-physician financial relationships that do not fall within one of the Stark exceptions. Once a hospital provides information on its RFR’s, CMS may be interested in reviewing these relationships in more detail.

As defined in the Stark law and regulations, all hospital services are DHS. Physicians who have a financial relationship with an entity that furnishes DHS are prohibited from referring patients for DHS unless their financial relationships fit within one of the Stark exceptions, and the penalties to the hospital for such prohibited referrals are severe. No Medicare bills may be issued for services based on a referral from a physician with a prohibited financial relationship with the DHS provider. If Medicare

has been billed, any payment the hospital has received is subject to recoupment as well as penalties. Thus, having a prohibited financial relationship with a physician can potentially result in millions of dollars in hospital losses. Stark is a strict liability statute: hospital-physician relationships must either comply with one of the exceptions or billing Medicare for referrals made by the physician is illegal.

Stark is a law which has not seen strong enforcement in the past. However, this may well change once the government gets the information it now intends to seek, with potentially catastrophic results, especially for those hospitals without a strong Stark compliance program.

We strongly recommend that hospitals prepare for the upcoming initiative by taking the following steps as quickly as possible:

1. Collect and Review

Gather information on all existing arrangements, written and unwritten, under which the hospital pays to or receives compensation from physicians or their immediate family, including: (i) independent contractor physician services agreements (e.g., payment for call, compensation for board service, payment of travel expenses, conference attendance); (ii) physician recruitment loan assistance/income guarantees; (iii) leases of office space, equipment, services or people *to or from* physicians, whether these leases are on a time, per-use, or other basis; (iv) management service contracts and joint venture arrangements; (v) exclusive contracts giving a physician or group the right to bill and collect in exchange for providing certain patient care services at the hospital; (vi) vendor agreements with physicians or immediate family (e.g., durable medical equipment, caterers, travel agents, recruiters, linen service).

2. Create a Master, Cross-Referenced List

If unwritten arrangements (other than *bona fide* W-2 employment) are found to exist, create written documentation immediately.

Ensure that all RFR agreements are cross-referenced on a master list that is updated on a rolling basis as agreements expire, are renewed, or added; ensure internal controls exist to approve agreements and ensure expiring contracts are flagged and payments stopped if not renewed.

Retain expired agreements for historical purposes, and keep list and underlying agreements current and in a file that can be produced for inspection upon notice from CMS or the OIG. Access to and oversight of the list and underlying agreements should be available to the compliance officer.

3. Ensure that Each RFR Fits within a Stark Exception

Once available for inspection, the documents may reveal some problems that lead directly to the next stage of compliance activities. We advise compliance officers to work with legal counsel to review each contract, lease, or services agreement to determine whether each complies with one of the Stark exceptions. Each exception has its own technical requirements, but the following are red flags: compensation that does not appear to be at *fair market value*; payments being made by A/P despite *expired contracts*; lease arrangements based on *outdated valuations*; compensation that is not *set in advance*, or payment that *varies with the volume or value* of DHS referrals or other business between the parties; lack of *specificity* about the type and quantity of services or items being provided (or worse, no evidence that the items or services are *actually being provided*). These would indicate that compliance activities and operational controls need to be stepped up going forward—and that legal counsel should be immediately involved. All hospital-physician financial relationships that do not fully comply with a Stark exception cause all referrals between the parties to be prohibited. As a result, every dollar the hospital has received from Medicare for services ordered by the physician can be recovered by the government with penalties.

This newsletter is one of a series of publications by Murtha Cullina LLP and should not be construed as legal advice or legal opinion on any specific facts or circumstances. The contents are intended for general information purposes only, and you are urged to consult your own lawyer concerning your own situation and any specific legal questions you may have.

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