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Patient Care versus Stark Compliance: The Impact of the "Under Arrangements" Restriction on Hospital Inpatient Care

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There May Be Other Options, But They Are Often Complicated and May Present Operational Hurdles

Many hospitals are finding that the 2009 Stark law restriction on "under arrangements" relationships has resulted in a troubling side effect by limiting the scope of patient care services that hospitals may provide to their *inpatients*. Generally, the Medicare program permits hospitals to contract with third parties to provide services under arrangements to the hospital's patients. This option is especially attractive when a hospital does not have necessary equipment or technological resources to provide certain critical services to its inpatient population. For example, it may be cost prohibitive for a hospital to invest in the equipment, technology, and staff necessary to provide radiation therapy to its oncology inpatients.

Prior to the 2009 change to the Stark law, the hospital would have been allowed to contract with an oncology group to provide the services and bill Medicare directly for the group's services as part of the inpatient diagnosis-related group (DRG). Due to the restriction on under arrangements relationships, however, this type of arrangement is no longer a viable option unless the hospital is located in a rural area.

While the Centers for Medicare & Medicaid Services' (CMS') desire to manage federal health care spending through restricting under arrangements relationships in the outpatient setting makes sense, as discussed below, it does not necessarily translate to the inpatient setting where Medicare reimbursement is largely dictated by the DRG. Therefore, it is unclear why CMS continues to apply the under arrangements restriction to inpatients and leads one to question whether CMS fully appreci-

ates the significant impact of the restriction on patient care.

Overview of the Stark Law and the "Under Arrangements" Restriction

The Stark law generally prohibits physicians from referring Medicare patients for designated health services (DHS), including inpatient and outpatient services, to an entity with which the physician or a member of the physician's immediate family has a financial relationship (ownership or compensation), unless an exception applies. The Stark law also prohibits an entity from presenting or causing to be presented a bill or claim to anyone for DHS furnished as a result of a prohibited referral.[1]

The Stark law is a strict liability statute and does not require any showing of intent in order for a violation to occur. Therefore, if a physician refers a Medicare patient for DHS to an entity with which the physician has an ownership or compensation relationship, the arrangement must be structured to meet an applicable exception to the Stark law.

Prior to the implementation of the Stark law restriction on under arrangements relationships, a physician's ownership interest in a company performing DHS under arrangements (such as the physician's practice) did not need to meet a Stark exception. This was due to the fact that CMS traditionally had defined the term DHS "entity" to include only the entity that *billed* Medicare for the DHS (*i.e.*, the hospital), not the company that provided the services under arrangements (*i.e.*, the physician's practice or other entity owned by the physician).

Because the Stark law only applies to financial relationships between physicians and DHS "entities," the physician's ownership interest in a company that merely provided, but did not bill for, DHS was not subject to the Stark law. Effective October 1, 2009, however, CMS broadened the definition of "entity" to include both the entity that *bills* for the DHS *and* the entity that *performs* the DHS.[2] Due to this expansion in the definition of the term "entity," the physician's ownership interest in a company that provides DHS under arrangements now needs to meet an ownership exception to the Stark law.

There are very few Stark exceptions available for physician ownership in DHS entities, and it appears that none would be applicable to DHS provided under arrangements to a hospital unless the services are provided in a rural area pursuant to the Stark law exception for rural providers. As a result, arrangements with physician-owned entities, such as physician practices, to provide DHS under arrangements to hospitals were essentially prohibited effective October 1, 2009.

Outpatient versus Inpatient Setting

When CMS introduced its proposed regulations restricting under arrangements relationships, it justified the change based on its concern about the risk of overutilization of "hospital *outpatient* services for which Medicare pays on a per-service basis."[3] In particular, CMS indicated that services furnished under arrangements to a hospital are "billed at higher *outpatient hospital PPS* rates, which not only costs the Medicare program more but also costs Medicare beneficiaries more in the form of higher deductibles and coinsurance."[4]

This same concern, however, is not generally relevant to the inpatient context where the hospital is reimbursed the same amount regardless of the volume of services provided to the inpatient (with the exception of outlier situations). Therefore, arguably there is no incentive for overutilization in an under arrangements relationship related to inpatients. If anything, the hospital would have an incentive to minimize costs in order to achieve maximum revenue.

Even though there are clear differences in the reimbursement methodologies for inpatient and outpatient hospital services, CMS refused to draw a distinction between

these types of services for purposes of applying the under arrangements restriction. CMS has specifically stated that "if an entity performs services that, pursuant to a contractual arrangement with a hospital or other provider, are ultimately billed as DHS, the entity will be considered to have furnished DHS, regardless of whether the services are billed as outpatient hospital services, inpatient hospital services, or some other category of DHS."[5] CMS did not provide an explanation for its position.

It is possible that CMS did not fully appreciate the significant impact that this change would have on inpatient care. CMS listed several alternatives available to hospitals and physician groups in lieu of providing services under arrangements, one of which related to services being provided and billed directly by the physician group rather than the hospital. CMS stated that it believed that "in many cases physician groups could provide the services and bill for them directly, that is, without the need to contract with a hospital to provide them 'under arrangements,' and that, to the extent the services would be DHS when performed and billed by the physician group, referrals to the physician entity could be protected by the in-office ancillary services exception or another exception."[6]

While this may be true in the outpatient setting where services could be billed by the physician group as clinic services rather than by the hospital as a provider-based outpatient service, this is certainly not a feasible approach for hospital inpatients. Because hospital reimbursement for inpatients is limited to the DRG, the physician group would not be able to bill directly for ancillary services provided to hospital inpatients. In order for the physician group to bill for the services, the inpatients would first need to be discharged by the hospital and transferred to the physician group to receive the services. Then the patients would need to be transferred back to the hospital and readmitted.

This is a questionable approach from a Medicare reimbursement perspective as well as raising concerns regarding the hospital's compliance with the Medicare conditions of participation. Additionally, even if the transfer is required to obtain necessary services, there are obvious patient care issues associated with a transfer that may not be in the best interest of the patient. The transfer also may subject the hospital to potential medical malpractice liability for inappropriate discharge.

Conclusion

Unfortunately, CMS has left little room for hospitals to arrange for patient care services for their inpatients in the wake of the implementation of the under arrangements restriction. Hospitals that are not located in rural areas are essentially limited to providing all services directly or transferring their inpatients to other facilities that are equipped to provide the services, regardless of the distance involved in such a transfer, the inconvenience to the patient, or other potentially detrimental patient care implications. While there may be other options available depending on the service involved, including but not limited to arrangements involving the lease of equipment or staff from a physician-owned entity, these options are often quite complicated and may present numerous operational hurdles.

Hospitals encountering this issue should consider requesting an advisory opinion from CMS. While it is not entirely clear how CMS would rule on this issue given its prior refusal to distinguish between inpatient and outpatient services, it is possible that CMS did not fully appreciate the negative impact the restriction would have on the efficient provision of inpatient care or the lack of alternatives available for inpatient under arrangements relationships. Now that the full effect of the change in the rule is being realized by hospitals and impacting the care provided to Medicare

beneficiaries, CMS may be more amenable to revisiting the issue, particularly considering that such arrangements are a low risk for overutilization and help facilitate quality inpatient care.

Endnotes:

1. 42 U.S.C. §1395nn.
2. 42 C.F.R. §411.351.
3. 73 FR at 48721 (Aug. 19, 2008) (emphasis added).
4. 72 FR at 38186 (July 12, 2007) (emphasis added).
5. 73 FR at 48733.
6. 73 FR at 48729.

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