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FEBRUARY 6, 2009

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On January 22, 2009, **CMS issued a Q&A** stating that in certain circumstances physician-owned lithotripsy companies can continue to use a percentage-based or per-use payment structure when providing lithotripsy services "under arrangements" to hospitals.

CMS had previously announced in its August 19, 2008 Stark final rules that use of per-service or percentage-based compensation would be prohibited for equipment leases effective October 1, 2009. This Q&A clarifies that the provision of lithotripsy services "under arrangements" to a hospital, which includes both the provision of a technician and the lithotripsy equipment, can continue to be treated as a service (rather than an equipment lease) and billed on a per-service basis under the new rules.

The Q&A specifically asks:

Where a physician-owned lithotripsy partnership contracts with a hospital to provide a lithotripter and skilled technician "under arrangements," may the hospital pay for such services using a per-use or percentage-based compensation formula without violating the physician self-referral law?

CMS first explained that lithotripsy is not considered a designated health service (DHS). As a result, if the physician owners refer to the hospital for lithotripsy services *only*, the Stark law would not be implicated. If, however, the physician owners of a lithotripsy partnership refer Medicare patients to the contracting hospital for any other DHS service, i.e., inpatient or outpatient hospital services, the arrangement falls within the purview of the Stark law and must comply with an exception.

CMS then explained that whether the per-service arrangement between the hospital and lithotripsy partnership will qualify for an exception will depend on the nature of the arrangement. To the extent that the lithotripsy partnership merely leases the lithotripter to the hospital, the arrangement using a percentage-based or per-service compensation formula would fail to comply with any of the applicable equipment lease exceptions to the Stark law, under the new rules effective October 1, 2009, and would not be permitted. To the extent, however, that the lithotripsy partnership provides both the services of a skilled technician and the use of the lithotripter, a per-unit or percentage-based compensation formula could be used under the personal services exception to

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the Stark law. CMS permits contractors to provide the "tools of their trade" in connection with service contracts and, therefore, the lease of equipment as part of a service contract can be compensated on a per-service basis and qualify for the personal services exception. That is, if the lithotripsy partnership is actually providing a service, i.e., services of a skilled technician, and not merely leasing equipment, a per-unit or percentage-based compensation formula is permitted as long as all other requirements of the applicable exception are met.

Ober|Kaler's Comments: It is important to note that CMS guidance set forth in Q&A 9556 applies only to physician-owned lithotripsy partnerships. Although the personal services exception can be utilized to permit the provision of other services with equipment components using the same analysis as lithotripsy, creating a package of technicians and equipment has further implications under the Stark law. In the August 19, 2009 Stark final rule, CMS expanded the definition of "DHS entity" to include both the entity that bills for the service and the entity that "performs" the service. Under the expanded definition, if a physician-owned company is providing a DHS service, rather than leasing equipment, the physicians will have an ownership interest in a DHS entity for which a Stark ownership exception would be required, if the physician refers patients for that service. The only applicable ownership exceptions are for rural areas and publicly traded companies. The personal services exception, which permits per-unit and percentage-based compensation, applies only to compensation arrangements, not ownership arrangements. This is not an issue for lithotripsy companies because, pursuant to court precedent, lithotripsy is not considered a DHS. Therefore, where a physician-owned company provides lithotripsy services, it is not a DHS service, and no ownership in a DHS entity is created.

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