CMS FAQ Offers Hope for Per-Click Lithotripsy Services Provided “Under Arrangements”

The 2009 Medicare IPPS Final Rule changed Stark’s space and equipment lease, fair market value and indirect compensation arrangement exceptions to prohibit per-click leases effective October 1, 2009. This change seemed the death knell for per-click lithotripsy services provided to hospitals "under arrangements." But, in a recent FAQ, CMS appears to throw a life line to such agreements. In the FAQ, CMS takes the position that such arrangements may be protected by Stark's personal services exception, thus avoiding the prohibition on per-click arrangements. However, the application of the FAQ to under arrangement agreements where the service provider furnishes more than "equipment or items incidental or peripheral to the provision of personal services" remains unclear. Further, it does not appear that the FAQ will save under arrangement agreements for services other than lithotripsy. Finally, the FAQ does not affect per click leases to ambulatory surgery centers. These leases are generally not covered by Stark, but do raise anti-kickback concerns.

CMS FAQ
The FAQ was published by CMS on January 22, 2009. In the FAQ, CMS acknowledges that lithotripsy, whether provided in a hospital or otherwise, is not one of the designated health services (DHS) covered by Stark. Notwithstanding that lithotripsy is not a DHS, if the physician owners of a lithotripsy provider refer other DHS to a hospital, the arrangement between a hospital and a lithotripsy provider needs to meet a Stark exception. Referencing the Stark Phase II Final Rule, CMS acknowledges that it is a common practice for many independent contractors to provide the “tools of their trade” in connection with their service contracts. In the preamble to the Stark II Final Rule, CMS took the position that it was not necessary to meet the equipment lease exception when an independent contractor uses the tools of their trade as part of a service contract. Similarly, if a lithotripsy provider is actually furnishing a service (or a package of services) to the hospital, and not merely leasing equipment over which the hospital would have dominion and control, a hospital may compensate a lithotripsy provider using a per-click compensation formula under Stark's personal services, fair market value or indirect compensation arrangement exceptions.

Bradley Arant Boult Cummings Commentary
A few caveats about CMS’ FAQ. First, the effect of the FAQ on arrangements where the services provider furnishes not only equipment but space is unclear. The IPPS Final Rule prohibits per-click equipment AND space leases effective October 1, 2009. The FAQ relies on CMS' long-held position that the use by an independent contractor of "tools of the trade" does not, by itself, require that an arrangement with the contractor meet Stark's equipment lease exception. However, in many lithotripsy arrangements (e.g., mobile lithotripsy arrangements), the lithotripsy provider also furnishes the space in which the lithotripsy is performed. Whether such arrangements must satisfy Stark's space lease exception and thereby remain subject to the per-click prohibition is an open question.
Second, CMS' position on "tools of the trade" was first articulated in response to comments to the Stark Phase II Proposed Rule. The commenters urged CMS to protect under the personal services exception equipment or items comprising only a minor component of an overall services arrangement. Given the narrow scope of the comments to which CMS was responding when it articulated its "tools of the trade" position, the general usefulness of the FAQ is questionable, particularly in arrangements where the use of the independent contractor's equipment represents a large component of the services provided to the purchasing hospital.

Third, the FAQ likely will not save under arrangements agreements for services other than lithotripsy. The 2009 Medicare IPPS Final Rule expanded Stark's definition of "entity." Previously, financial relationships between entities that performed, but did not bill, for DHS did not implicate Stark. Effective October 1, 2009, the definition of DHS "entity" expands to include not only those billing for DHS, but also those performing DHS. Where one entity performs DHS that is billed by another entity, both entities are DHS entities with respect to the service, and any financial relationship between a referring physician and the performing entity must meet an exception. Because lithotripsy is not DHS (whether provided by a hospital or otherwise), the definition of entity should have little effect on an entity that provides only lithotripsy services. However, if the performing entity performs DHS, the financial relationship between the performing entity and its owners must meet a Stark exception. Typically, the only ownership interest exception available is the rural provider exception. Accordingly, under arrangements agreements for non-lithotripsy services with referring physicians that do not draw substantially all of their patients from rural areas will be prohibited, notwithstanding the FAQ.

For more information on the FAQ and its affect on under arrangement agreements, please feel free to contact any member of the Bradley Arant Boult Cummings Health Care Team.