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Court Strikes Down Per-Click Restrictions, or Does It?

One of the government's tools for combating fraud and abuse in the healthcare industry is the *Stark Law*, also known as the self-referral law. In its continual efforts to protect individuals from healthcare fraud, the *Centers for Medicare and Medicaid Services* (CMS) has periodically sought to broaden the law and further define the various types of fraud that may occur in the healthcare industry. Recently, the per-click fee restriction included in *Stark IV* has come under fire in the D.C. Circuit for exceeding the statutory authority of the *U.S. Department of Health and Human Services* (HHS). To understand the court's decision and its implications, it is important to understand both the history of the *Stark Law* and the history of the case itself.

The *Stark Law* was initially designed to prevent physician self-referrals, which potentially encourage the over-utilization of healthcare services and increase healthcare costs. The original *Stark Phase I* (out of four phases), was introduced in the *Omnibus Budget Reconciliation Act of 1989* (OBRA 1989), and became effective in 1992.[1] *Stark I* allowed physicians with an ownership interest in an equipment leasing company to refer patients to that company and receive a fee for each patient that used the physician-owned equipment.[2] Physicians who owned these leasing companies were eligible to receive payments because of a "*loophole*" in *Stark I* that only forbade reimbursement for the entity or individual that directly billed Medicare for that *designated health service* (DHS), in contrast to forbidding reimbursement to the entity or individual that performed the DHS.[3]

Since *OBRA 1989*, *Stark Phase I* has been expanded to *Stark Phases II, III,* and now *IV*, with each phase adding more modifications and restrictions than the previous phase.[4] As part of *Stark IV*, regulators added restrictions for diagnostic imaging arrangements based on concerns that physicians' equipment lease arrangements with hospitals promoted over-utilization of their own equipment and shifted the focus away from patient need and toward financial gain.[5]

In *Stark IV*, CMS restricted the ability of physicians to use a unit-of-service, or "*per-click*," fee payment system for space or equipment leases with a hospital to which the physician refers patients.[6] A per-click arrangement is one in which a physician or healthcare entity leases equipment to another healthcare organization and receives a fee each time the equipment is used. Importantly, *Stark IV*, which was adopted in the *Inpatient Prospective Payment Systems Fiscal Year 2009 Final Rule* (IPPS Rule) in August 2008, prohibits physicians who refer any patients to a hospital from leasing equipment to that facility on a per-click basis.[7] The *IPPS Rule* essentially changed the definition of "*entity*" to include both the entity or the individual *billing* Medicare for the DHS and the entity or individual *performing* the DHS.[8] This language change indicates that physicians who referred patients to hospitals that used their equipment were now referring patients to their own company, creating a self-referral payment system that would violate *Stark Law* unless an exception applied.[9] However, the *IPPS Rule* specifically noted that per-click fee arrangements no longer fit within the exceptions to the prohibitions on lease arrangements, including the *lease exception*, the *fair market value exception*, and the *exception for indirect compensation arrangements*, "*to the extent that these charges reflect services provided to patients referred between the parties*."[10] The per-click part of the rule went into effect on October 1, 2009,[11] giving physicians a year from publication to restructure or eliminate any operational per-click arrangements with hospitals to meet the new compliance standards.[12]

After CMS released the updated regulations, some physicians disagreed with the new restrictions in the *IPPS Rule* and accused HHS of overstepping its statutory authority.[13] In 2009 in the district court of D.C., the *Council for Urological Interests*, a urologist-owned group of joint ventures that leased laser technology to hospitals, brought a lawsuit against the Secretary of HHS arguing that the per-click restrictions and definition change of "*entity*" violated the *Administrative Procedure Act* and the *Regulatory Flexibility Act* and overstepped HHS's authority under *Stark Law* because the changes prohibited the urologists from providing laser treatment to Medicare patients.[14] The D.C. district court dismissed the case in December 2010 on jurisdictional grounds, but, on appeal, the decision was reversed and remanded back to the district court for further proceedings.[15] Upon rehearing the case, the district court again found in favor of the Secretary, granting her motion for summary judgment based on the finding that (1) HHS's interpretation of performing

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DHS was reasonable and consistent with the statutory purpose of *Stark Law* (i.e., prohibiting physician self-referrals); and, (2) the prohibition on per-click payments was valid.[16]

However, on appeal from that decision, the D.C. Circuit Court of Appeals held that although (1) the Secretary was *not* barred from prohibiting physicians from charging hospitals for leased equipment on a per-click basis; and, (2) that the new definition of "*entity*" was *reasonable*, the Secretary's interpretation of the *Stark Law*, i.e., that it barred physicians from charging a hospital for equipment on a per-click basis when those physicians also referred patients to that facility for procedures, was *unreasonable*.[17] The court remanded the case back to the district court, with instructions to send the issue to the Secretary herself for consideration, "*with more care than she exercised here*," of whether the per-click ban was consistent with the *1993 House Conference Report* on which she relied in her argument.[18] The D.C. Circuit expressed bewilderment regarding the Secretary's explanation of why the per-click restriction was valid, i.e., "*because per-unit rates caused the total amount of the lease to fluctuate over the term based on volume and therefore did not meet the statutory 'set in advance' requirement*."[19] The court noted that the Secretary's interpretation of the 1993 report seemed to ignore some of the language within it,[20] pointing out that the report "*makes clear that the 'units of service rates' are what cannot 'fluctuate during the contract period,' not the lessor's total rental income*."[21]

With the case currently on remand to the HHS Secretary, there is speculation in the healthcare industry surrounding how HHS will interpret, and whether it will enforce, the per-click restrictions. One option is that the HHS Secretary may choose not to re-address the per-click issue, thus implicitly allowing per-click fee arrangements.[22] HHS may also use the *Office of Inspector General* (OIG) to issue guidance or an enforcement action on the issue, or even relate such fee arrangements to the *Anti-kickback Statute*.[23] HHS may choose to interpret the language in a way that maintains the restriction's validity by focusing on its authority to issue regulations as needed in order to guard against patient and/or program abuse.[24] Given the variety of outcomes that may occur as a result of the court's decision, physicians and hospitals would be well served to proceed cautiously when considering equipment leasing arrangements.

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