

THE “CROSS-YOUR-FINGERS-AND-HOPE-IT-GOES-AWAY” SCHOOL OF STATUTORY INTERPRETATION”: RECENT D.C. CIRCUIT OPINION ORDERS HHS TO RECONSIDER STARK LAW BAN ON “PER-CLICK” LEASE PAYMENTS

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Health Care Alert

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On June 12, 2015, the U.S. Court of Appeals for the District of Columbia (the "Court") issued an opinion questioning the Department of Health & Human Services' ("HHS") interpretation of congressional intent when it promulgated regulations banning certain "per-click" lease arrangements.[1] Specifically, through its 2008 amendment to the regulations implementing the federal Physician Self-Referral Law (the "Stark Law"), HHS prohibited physicians who lease equipment to hospitals and charge on a per-unit basis from referring their Medicare patients to those hospitals for services involving that equipment.

The lengthy opinion undertakes an "arduous journey through the tangled regime" of Medicare statutory provisions and regulations, ultimately concluding that the Secretary of HHS (the "Secretary") failed to explain a reasonable and permissible interpretation of congressional intent when promulgating such a ban.[2]

BACKGROUND LAW

The Stark Law generally prohibits physicians from referring Medicare patients to entities with which the physician or a family member has a financial interest.[3] The prohibition applies to referrals for "designated health services," defined to include inpatient and outpatient hospital services and outpatient prescription drugs, among other things.[4] If the Stark Law applies, an entity furnishing those services may not bill Medicare for any services referred by the physician unless an exception applies. One such exception to the Stark Law is the equipment rental exception, which provides that certain equipment lease arrangements between a physician and the entity will not be considered a prohibited financial relationship ("Equipment Rental Exception"). Under the Equipment Rental Exception, a physician may lease equipment to a hospital and still refer Medicare patients to the hospital for procedures using that equipment, as long as the lease agreement meets all required conditions. Specifically, among other conditions, the rental charges over the term of the lease must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.[5] The statutory exception further provides that "the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse." [6] In 2008, the Secretary amended the Equipment Rental Exception to also prohibit equipment leases in

which a physician-lessor charged a hospital-lessee a rental rate for each use of the equipment, referred to as a "per-click" payment, finding that such arrangements present a "burgeoning risk of abuse and increased costs to the Medicare program." [7]

FACTS

The Council for Urological Interests (the "Council") is composed of a group of physician-owned, joint ventures that enter into lease agreements with hospitals for the use of laser technology equipment, in which the hospitals pay the joint venture for the equipment on a per-click basis. Following the 2008 ban on per-click lease arrangements, the Council filed an action against the Secretary alleging that the ban exceeded the Secretary's authority. The Council argued that both the text and legislative history of the Stark Law clearly establish Congress's intent to protect per-click lease arrangements between physicians and hospitals, and that the Secretary unreasonably interpreted the statute when prohibiting per-click leases.

Legislative and Regulatory History at Issue

In 1998, HHS initially proposed a rule that would prohibit "per-click" equipment lease payments. However, the proposed ban was not promulgated in the 2001 final Stark Law regulations ("2001 Final Rule"). Instead, the 2001 Final Rule states that the 1998 proposed rule was modified in order to reflect a 1993 congressional Conference Committee report ("Conference Report"). [8] In relevant part, the cited Conference Report provides:

The conferees intend that charges for space and equipment leases may be based on daily, monthly, or other time based rates, or rates based on units-of-service furnished, so long as the amount of the time-based or units-of-service **rates** does not fluctuate during the contract period based on the volume or value of referrals between the parties to the lease or arrangement. [9]

After analyzing such congressional intent, the 2001 Final Rule concludes that "given the clearly expressed congressional intent in the legislative history, we are permitting 'per use' payments." [10] The 2001 Final Rule further explains:

We have reviewed the legislative history with respect to the exception for space and equipment leases and concluded that the Congress intended that time-based or unit-of-service-based payments be protected, so long as the **payment per unit** is at fair market value at inception and does not subsequently change during the lease term in any manner that takes into account DHS referrals. [11]

However, in 2007, the Secretary reconsidered per-click lease arrangements, again proposing to ban such time-based or unit-of-service-based payments between a physician-lessee and hospital-lessor. This time, the prohibition was finalized in the 2008 final rule (the "2008 Final Rule"). [12]

In the 2008 Final Rule, the Secretary explains that "upon further analysis of the legislative history, we no longer believe that the interpretation we adopted in the Phase I final rule is the only reasonable interpretation of the statute and legislative history."^[13] The 2008 Final Rule continues by concluding that if "the total amount of rent (that is, the rental charges)" is directly affected by the volume of patients referred by the physician to the hospital, then the rental charges "can arguably be said to 'take into account' or 'fluctuate during the contract period based on' the volume or value of referrals between the parties."^[14]

COURT FINDINGS

In *Council for Urological Interests v. Burwell*, the Court acknowledged the broad authority of HHS to interpret the Stark Law statute, applying the deferential *Chevron* test when reviewing the agency's regulations.^[15] The two-step *Chevron* test considers whether Congress has "directly spoken to the precise question at issue," and subsequently, if the statute is silent or ambiguous on the issue, whether the agency's statutory interpretation is "a 'permissible' and 'reasonable' view of the Congress's intent."^[16] Under the first prong of the test, a majority of the Court concluded that the statute is silent regarding the permissibility of per-click leases, and further recognized that Congress clearly gave the Secretary broad discretion in regulating the equipment rental leases at issue.^[17]

However, when analyzing whether HHS's interpretation of the Stark Law was reasonable and permissible under the second prong of the *Chevron* test, the Court concludes that "the per-click ban falters." In reaching this conclusion, the Court focused on HHS's inconsistent and "incomprehensible" explanations of the legislative history:

In the preamble to the [2008 Final Rule] per-click ban, the Secretary identified the 1993 Conference Report as an important locus of statutory interpretation... This is unsurprising as the Secretary felt completely bound by the Conference Report in 2001... The Secretary now believes the Conference Report is ambiguous but her explanation in the 2008 rulemaking borders on the incomprehensible.^[18]

The Court analyzes the 2008 Final Rule commentary interpreting the Conference Report as "plainly not a reasonable attempt to grapple with the Conference Report; it belongs instead to the cross-your-fingers-and-hope-it-goes-away school of statutory interpretation."^[19] The Court further notes that the Conference Report is clear that "units of service *rates*" may not fluctuate during the contract period, not the lessor's total rental income, and comments that the Secretary's interpretation "reads the word 'rates' out of the Conference Report entirely."^[20] The Court finally concludes that the Secretary's "bewildering statutory exegesis" cannot be affirmed, even under the *Chevron* test's deferential standard of review, and remanded the regulation back to the Secretary to reconsider "with more care than she exercised here" whether a ban on per-click equipment leases is consistent with congressional intent.^[21]

The Council also challenged HHS's new definition of an "entity furnishing designated health services," which now includes both the entity "performing" and the entity "billing" the designated health service ("DHS").^[22] Previously, CMS guidance indicated that only the entity billing Medicare for the DHS was subject to the Stark Law prohibition on referrals.^[23] In the 2008 Final Rule, CMS modified the definition to also include entities that "perform" the

DHS—though CMS declined to further clarify what it means to "perform" a service, intending that the term has its common meaning.[24] The Court upheld the new definition in the 2008 Final Rule, concluding that HHS reasonably construed the statute when redefining the term "entity furnishing the designated health service."

Beyond its conclusion in this regard, however, the Court's actual legal analysis in response to the Council's arguments is hard to fathom, and it is difficult to discern from the opinion which of the two went off track first. For instance, the Council argues that the new definition of "entity" is contrary to legislative intent "because it deprives the exception for group practices of all effect." [25] Without questioning the correctness of this assertion, the Court instead counters that the 2008 Final Rule purposefully "significantly narrows the exception for group practices." [26] Specifically, the opinion indicates that following the 2008 Final Rule, a group practice that is providing services to a hospital under contract is considered an entity "furnishing" the services, and, thus, individual physician owners in the group practice will not be permitted to refer patients to the hospital unless an ownership exception applies. [27] This conclusion would not seem to be correct unless the group is providing the service through a turnkey "under arrangement" type contract, and, regardless, the group would have been a DHS entity in most circumstances in its own right. Moreover, an ownership exception would be available to the group if the group was properly structured. However, neither the Council nor the Court explain how this discussion specifically relates to, or is impacted by, the new definition of "entity," nor does the opinion bother to offer an explanation differentiating physician group practices under the Stark Law regulations from joint ventures with physician ownership, such as many of the Council's constituents. The Court also fails to make clear that under the 2008 Final Rule, a physician-owned joint venture that only provides equipment to a hospital through a leasing agreement would not be held to "perform" or "furnish" the DHS under the new definition. [28] Suffice it to say that although the Court is exceptionally critical of HHS's statutory construction of the per-click lease ban, its own analysis of the Stark Law regulations in upholding the expanded definition of "entity" is similarly nonsensical.

KEY TAKEAWAYS

In its analysis of the 2008 Final Rule, the Court noted the inconsistent and "tortured reading" of the congressional intent behind the Equipment Rental Exception. [29] On remand, it is clear that HHS will have to find some other commentary in the Conference Report on which to base a per-click ban. Such support might be found in statements related to the congressional intent to prohibit financial incentives and the potential for over-utilization, which are inherent in per-click lease arrangements. Even if the per-click rate does not change during the term of the lease, the physician-lessor may nevertheless be financially motivated to make referrals. Failing that, HHS may need to re-promulgate the ban on per-click lease arrangements as a result of its reliance on the Conference Report and following the Court's derisive commentary of the agency's statutory interpretation.

NOTES:

[1] *Council for Urological Interests v. Burwell*, No. 1:09-cv-00546, 2015 WL 3634632 (D.C. Cir. June 12, 2015).

[2] *Id.* at *1.

[3] 42 U.S.C. § 1395nn. A "financial interest" includes an indirect or direct ownership or investment interest, or a compensation arrangement with a hospital or entity; see generally 42 C.F.R. § 411.354.

[4] 42 C.F.R. § 411.351.

[5] 42 U.S.C. § 1395nn(e)(1)(B).

[6] *Id.*

[7] 73 Fed. Reg. 48,434, 48,716 (Aug. 19, 2008).

[8] H. Rep. No. 213, 103rd Cong., 1st Sess. 814 (1993).

[9] *Id.* (emphasis added).

[10] 66 Fed. Reg. 856, 878 (Jan. 4, 2001).

[11] *Id.* at 876 (emphasis added).

[12] See 73 Fed. Reg. 48,434 (Aug. 19, 2008); see also 42 C.F.R. § 411.357(b)(4)(ii)(B).

[13] 73 Fed. Reg. at 48,715.

[14] *Id.* at 48,716.

[15] See *Council for Urological Interests v. Burwell*, No. 1:09-cv-00546, 2015 WL 3634632, at *5 (D.C. Cir. filed June 12, 2015) (citing *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 860, 104 S. Ct. 2778, 2790 (1984)).

[16] *Council for Urological Interests*, 2015 WL 3634632, at *5, *8 (quoting *Chevron*, 467 U.S. at 843–44.)

[17] Though a majority concluded that the Stark Law is silent as to a per-click ban, a minority of the Court dissents, arguing that Congress "unambiguously intended to authorize per-click equipment leases," and thus the per-click ban fails the first step of the *Chevron* test. *Council for Urological Interests*, 2015 WL 3634632, at *12.

[18] *Council for Urological Interests*, 2015 WL 3634632, at *8.

[19] *Id.*

[20] *Id.* (citing H.R. Rep. No. 103-213, at 814).

[21] *Id.* at *9.

[22] *Id.*

[23] 66 Fed. Reg. 856, 913 (Jan. 4, 2001) ("we are revising our definition of 'entity' to clarify that a person or entity is considered to be furnishing DHS if it is the person or entity to which we make payment for the DHS").

[24] 73 Fed. Reg. 48,434, 48,721 (Aug. 19, 2008) ("a person or entity is considered to be 'furnishing' DHS if it is the person or entity that has performed the DHS, (notwithstanding that another person or entity actually billed the services as DHS) or presented a claim for Medicare benefits for the DHS. Note that where one entity performs a service that is billed by another entity, both entities are DHS entities with respect to that service.")

[25] *Council for Urological Interests*, 2015 WL 3634632, at *10.

[26] *Id.*

[27] *Id.*

[28] 73 Fed. Reg. at 48,726 ("We do not consider an entity that leases or sells space or equipment used for the performance of the service, or furnishes supplies that are not separately billable but used in the performance of the medical service, or that provides management, billing services, or personnel to the entity performing the service, to perform DHS.")

[29] *Council for Urological Interests*, 2015 WL 3634632, at *8.

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