UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

COUNCIL FOR UROLOGICAL INTERESTS, **Plaintiff,** **v.** **KATHLEEN G. SEBELIUS, in her official capacity as Secretary of the Department of Health and Human Services, *et al.*,** **Defendants.**	**Civil Action No. 09-cv-0546 (BJR)** **Re Document Nos.: 28, 30**

DENYING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT;
GRANTING DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT

This case is before the Court on cross-motions for summary judgment filed by Plaintiff, the Council for Urological Interests ("CUI"), and Defendants, the Secretary of the Department of Health and Human Services and the United States.[1] CUI alleges that recent regulations implemented by the agency violate the Administrative Procedure Act ("APA") and the Regulatory Flexibility Act ("RFA"). Having reviewed the briefs, the Administrative Record, and the relevant statutory provisions and regulations, the Court denies Plaintiff CUI's motion and grants Defendants' motion.

[1] Secretary Sebelius is sued in her official capacity as the administrator of the Medicare program. The Secretary of Health and Human Services has authority to promulgate regulations implementing the Medicare program. 42 U.S.C. §§ 1395hh(a), 1395nn(b)(4). The Secretary has delegated this authority to Centers for Medicare and Medicaid Services ("CMS"), a division of the Department of Health and Human Services. *See* Pl.'s Mot. at 1; 73 Fed. Reg. 48,434. As the Secretary is sued in her official capacity, this opinion will refer to Defendants in the singular, as "CMS" or "the agency" throughout.

I. BACKGROUND

A. Urologist-Owned Joint Ventures and Their Provision of "Under Arrangements" Services

CUI is a not-for-profit corporation comprised of businesses that provide equipment and technical personnel for performing various urological medical services. Compl. ¶ 2. The equipment and technical personnel provided by CUI's members are used to treat conditions such as non-cancerous prostate enlargement, prostate cancer, and related urological conditions. Pl.'s Statement of Facts ("SOF") ¶ 1.[2] One of the urological services used to treat such conditions is laser surgery. *Id.* ¶¶ 3-6.

According to CUI, laser surgery is more effective than open surgery in treating prostate and urological disease, but the technology is costly and requires frequent updating.[3] Compl. ¶¶ 3-6; 9-11. CUI claims that due to the cost, hospitals have been reluctant to invest in laser surgery equipment. *Id.* ¶ 11. Instead, urologists have formed joint ventures to purchase the laser surgery equipment. CUI's members consist largely of these urologist-owned joint ventures. *Id.*

The joint ventures frequently enter agreements with hospitals by which a joint venture leases to the hospital the equipment and technical personnel that are then used by the urologist-owners of the joint venture to perform outpatient laser surgery. *Id.* ¶ 18; AR 863. The services provided under such an agreement are commonly referred to as services made "under arrangements." In an "under arrangement" transaction, the hospital contracts with the urologist-

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[2] CMS disputes all of the facts asserted by CUI as not properly based on the Administrative Record. *See* Def.'s Response to Pl.'s SOF ¶¶ 1-22. The Court does not rely on any disputed facts in resolving this dispute.

[3] CUI explains that the typical cost of a laser averaged between $120,000 and $130,000, and that technological advances mean that a laser is obsolete in as little as two and a half years. Pl.'s SOF ¶¶ 7-8.

owned joint venture (or any other third party), for the performance of a hospital service, but it is the hospital that is responsible for billing and collecting payments. *See* 42 U.S.C. § 1395x(w).

As prostate conditions primarily affect older men, approximately 75% of patients who receive laser surgery from these joint ventures have insurance coverage through the Medicare program. Pl.'s SOF ¶¶ 1, 16. Thus, it is common that the hospital bills Medicare for the urological services. Medicare reimburses the hospital for the use of its equipment, space and non-physician personnel by paying a "technical fee."[4] The hospital, in turn, will pay the urologist-owned joint venture a previously contracted amount to account for the hospital's use of the joint venture's equipment and technical personnel in rendering the urological service. *See* Compl. ¶¶ 19-20; Def.'s Mot. at 6. This amount, commonly referred to as a "per-click" payment, is paid by the hospital to the joint venture each time that a service is performed "under arrangements."

As will be elaborated below, recent changes in the law have interrupted the ability of the urologists who own these joint ventures to refer their patients to receive services made "under arrangements." CUI has thus brought suit against CMS, asserting that these recent changes in the law violate the APA and the RFA. To further appreciate CUI's claims, however, a more thorough understanding of the relevant legal framework is required.

B. Legal Framework

1. The Stark Law

This litigation plays out against the backdrop of the Medicare Act—the vast federal statute that provides federal financial support for disabled persons and persons over the age of 65. 42 U.S.C. § 1395 *et seq.* Medicare provides a system for paying physicians, hospitals, and

[4] Medicare pays two types of fees in connection with services that are provided in a hospital: (1) a "professional fee" to the physician and (2) a "technical fee" to the hospital for the use of the equipment, space and non-physician staff. *See* 42 U.S.C. § 1395W-4(a)(1); *id.* § 1395x(s)(2).

prescription drug providers for patient care. *Id.* Early in the law's history, it became evident that abuse of the system could occur. One of the key areas of concern was that of "physician self-referrals"—patient referrals by a physician to a facility with which that physician had a financial relationship. Medicare and Medicaid Programs; Physician's Referrals to Health Care Entities With Which They Have Financial Relationships, 63 Fed. Reg. 1659, 1661 (proposed Jan. 9, 1998). Congress was concerned that a physician's financial interest could "affect [his or her] decision about what medical care to furnish a patient and who should furnish the care." *Id.* Simply put, Congress was worried that a physician who had a financial interest in a facility would refer patients to that facility in order to make money, rather than to provide the best course of treatment. *Id.*

In 1989, Congress responded to the issue of physician self-referrals by enacting the Stark Law, named after its sponsor, Congressman Fortney "Pete" Stark and codified at 42 U.S.C. § 1395nn. *Am. Lithotripsy Soc'y v. Thompson*, 215 F. Supp. 2d 23, 26 (D.D.C. 2002). In its original form, the Stark Law responded to abuses in the use of clinical laboratories. The law prohibited a physician who had a financial relationship with a clinical laboratory from making a referral to that same laboratory for the furnishing of services that Medicare would pay for. 63 Fed. Reg. at 1661. Four years later, in 1993, Congress expanded the Stark Law from the clinical laboratory context, naming eleven other types of services where physician self-referrals would be prohibited. *Am. Lithotripsy*, 215 F. Supp. 2d at 26. Together, these twelve categories are referred to in the Stark Law as "designated health services" ("DHS"). Of specific relevance here, one of these DHS categories is "[i]npatient and outpatient hospital services." 42 U.S.C. § 1395nn(h)(6)(K).

In its current form, the Stark Law states that "if a physician . . . has a financial relationship with an entity . . . then the physician may not make a referral to the entity for the furnishing of a [DHS] for which payment otherwise may be made under [the Medicare Act]." 42 U.S.C. § 1395nn(a)(1)(A). Moreover, if a referral is prohibited under § 1395nn(a)(1)(A), "the entity may not present or cause to be presented" a Medicare claim for the DHS that was received. 42 U.S.C. § 1395nn(a)(1)(B).

A "financial relationship" is defined as either (1) a physician's "ownership or investment interest in the entity" or (2) a "compensation arrangement . . . between the physician and the entity." 42 U.S.C. § 1395nn(a)(2)(A)-(B). An "ownership or investment interest . . . may be through equity, debt or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service." *Id.* § 1395nn(a)(2)(B). "The term 'compensation arrangement' means any arrangement involving any remuneration between a physician . . . and an entity." *Id.* § 1395nn(h)(1). Thus, the Stark law prohibits a physician who owns an entity or has entered into a payment arrangement with an entity from referring his or her patients to that entity for DHS.

2. Relevant Regulatory Background

a. 2001 Regulations

Congress delegated authority to the Secretary to promulgate regulations implementing the Stark Law. *See, e.g.*, 42 U.S.C. §§ 1395nn(b)(4). In 2001, CMS promulgated regulations that defined "outpatient hospital services" as "includ[ing] services that a hospital provides for its patients that are furnished either by the hospital or by others under arrangements with the hospital." 42 C.F.R. § 411.351 (2001). In other words, as of the 2001 Regulations, services performed "under arrangements" with a hospital would qualify as "outpatient hospital services" for purposes of the Stark Law. *See id.* Because "under arrangement" services are "outpatient

hospital services," and because, as discussed earlier, the Stark Law expressly provides that "outpatient hospital services" are DHS, it follows that services performed "under arrangements" are DHS. Accordingly, under the 2001 Regulations, services provided "under arrangements" (including urological services performed by urologist-owned joint ventures) are subject to the Stark Law's prohibition on physician self-referrals. *See* 66 Fed. Reg. at 923.

In addition to defining "outpatient hospital services," the 2001 Regulations also clarify what the term "entity" means under the Stark Law, which is not defined in the statute. "Entity" refers to a physician's sole practice, group of physicians, or other organization (like a corporation, partnership, etc.) that "furnishes DHS." 42 C.F.R. § 411.351 (2001). Moreover, under the 2001 Regulations, "[a] person or entity is considered to be furnishing DHS if it is the person or entity to which CMS makes payment for the DHS, directly or upon assignment on the patient's behalf." *Id.* In other words, an entity furnishing DHS was limited to only the person or entity that was billing Medicare. This narrow definition was significant to urologists who owned joint ventures because, as the joint venture was not billing Medicare, the urologist-owners remained free to refer Medicare patients to the joint venture for DHS. *See* 42 U.S.C. § 1395nn(a)(1)(A).

Lastly, in the 2001 Regulations, CMS interpreted the Stark Law's compensation arrangement exceptions to allow for "per-click" payment arrangements. 66 Fed. Reg. at 876. As noted above, every time that a urologist-owned joint venture conducted a urological service "under arrangements" for a Medicare patient, the hospital – after obtaining reimbursement from Medicare – would pay the joint venture a previously contracted "per-click" payment for the use of the joint venture's equipment and technical personnel. *See supra* Part.I.A. These "per-click" payments were allowed even when the Medicare claim stemmed from DHS performed on a

patient that the urologist-owner had referred to the joint venture, and notwithstanding the Stark Law's general prohibition on physician self-referrals. 66 Fed. Reg. at 876-78; 42 C.F.R. § 411.354(d)(1)-(4). Thus, under the 2001 regulatory regime, urologist-owners were allowed to make referrals to their own joint-ventures— referrals that would result in per-click lease payments to the joint venture and, by extension, the urologist-owners.

b. 2008 Regulations

In 2008, CMS revised the regulations in two ways that created challenges for the urologist-owned joint ventures. First, CMS expanded what it meant to be an entity furnishing DHS. Under this change, the Stark Law would treat as an entity that furnishes DHS, not only the organization that presented a Medicare claim for the DHS (*i.e.*, the billing organization), but also the organization that performed the DHS for which Medicare was billed. 42 C.F.R. § 411.351. By expanding the definition of an "entity furnishing DHS," the 2008 regulations brought physician-owned joint ventures within the ambit of the Stark Law's prohibitions, because a joint ventures performed DHS. Further, because the joint venture was an "entity" in which the urologist-owner had a financial interest, the 2008 Regulations effectively prohibited a urologist-owner from referring his or her Medicare patients for DHS to the joint venture working "under arrangements" with the hospital.

To understand the next revision that CMS made in the 2008 Regulations, it is important to note that the Stark Law provides exceptions to the general ban on physician self-referrals. 42 U.S.C. § 1395nn(b)-(e). Certain exceptions apply only where the physicians have an ownership or investment interest in the entity, *id*. § 1395nn(c)-(d), while other exceptions apply only when a physician and an entity have a compensation arrangement, *id*. § 1395nn(e). Of particular relevance here, the Stark Act allows a physician to make referrals to an entity with which he has

a compensation arrangement if the physician and the entity have entered into a lease agreement for the rental of office space or equipment, and if that lease agreement meets certain conditions. *Id.* § 1395nn(e)(1). Among these conditions, the "rental charges over the term of the lease . . . [must] not [be] determined in a manner that takes "into account the volume or value of any referrals," and "the lease must meet other requirements imposed by the Secretary's regulation as needed to protect against program or patient abuse." 42 U.S.C. § 1395nn(e)(1)(A)-(B). The Stark Law does not elaborate as to what it means for a rental charge to not take into account the volume or value of referrals.

The 2008 Regulations amended the regulations governing the lease agreement exceptions, prohibiting "per-click" rental charges "to the extent that such charges reflect services provided to patients referred between the parties." [5] 42 C.F.R. § 411.357(b)(4)(ii)(B). Accordingly, a joint venture providing DHS services "under arrangements" with a hospital would not be allowed to collect a "per-click" payment for each service to a Medicare patient if that patient had been referred to the joint venture by a urologist-owner.

CMS delayed the effective date of the 2008 Regulations by approximately one year to allow physicians and hospital time to restructure existing contracts. 73 Fed. Reg. 48,713; *id.* at 48,733.

C. Procedural History

In response to the 2008 Regulations, CUI filed this suit on March 23, 2009. *See generally* Compl. Judge Henry Kennedy dismissed the case on jurisdictional grounds, *Council for Urological Interests v. Sebelius*, 754 F. Supp. 2d 78 (D.D.C. 2010), but the D.C. Circuit

[5] The 2008 Regulations also prohibited "per-click" rental charges in the context of other compensation arrangement exceptions. *See* 42 C.F.R. § 411.357(l)(3)(ii) (amending regulations for the fair market value exception); 42 C.F.R. §411.357(p)(1)(i)(B) (amending regulations for the indirect compensation arrangements exception).

reversed and remanded for further proceedings, *Council for Urological Interests v. Sebelius*, 668 F.3d 704, 712-14 (D.C. Cir. 2011). In December 2011, the matter was reassigned to the undersigned judge.

Both parties have filed cross-motions for summary judgment. With those motions ripe for consideration, the Court turns to consider the parties' arguments and the applicable legal standards.

II. LEGAL STANDARDS

A. Summary Judgment under Federal Rule of Civil Procedure 56

The parties have cross-moved for summary judgment under Federal Rule of Civil Procedure 56, which provides for entry of summary judgment if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In a case involving the review of a final agency action under the Administrative Procedure Act, 5 U.S.C. § 706, the role of the district court is "to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Stuttering Found. of Am. v. Springer*, 498 F. Supp. 2d 203, 207 (D.D.C. 2007) (quoting *Occidental Eng'g Co. v. INS*, 753 F.2d 766, 769-70 (9th Cir. 1985)). In such cases, summary judgment serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review.[6] *Id.*

[6] The parties submitted Statements of Material Facts pursuant to Federal Rule of Civil Procedure 56 and Local Civil Rule 7(h). While the parties also submitted responses disputing one another's statements of facts, they acknowledged that neither believed there to be genuine issues of material fact that would necessitate a trial. *See* Def.'s SOF (Dkt. #30) at 6; Pltf.'s Response to Def.'s SOF (Dkt. #32) at 1. In any event, "where review is based on an administrative record the court is not called upon to determine whether there is a genuine issue of material fact, but rather to test the agency action against the administrative record." Comment to LCvR 7(h) (2008 Amendment).

B. Administrative Procedure Act

Under the APA, a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A), (C). "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

When reviewing the substance of an agency's interpretation of a law it administers, the court must apply the principles of *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Under *Chevron*, the first step begins with the statute. The court must examine the statute to determine whether Congress has spoken directly to the precise question at issue. *Natural Res. Def. Council v. EPA*, 643 F.3d 311, 322 (D.C. Cir. 2011). Such an examination requires the court to use "the traditional tools of statutory interpretation—text, structure, purpose, and legislative history." *Consumer Elecs. Ass'n v. FCC*, 347 F.3d 291, 297 (D.C. Cir. 2003) (quoting *Pharm. Research & Mfs. of Am. v. Thompson*, 251 F.3d 219, 224 (D.C. Cir. 2001)). Once the court determines that Congress has directly spoken to the precise issue, that is the end of the analysis, "for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842-43.

If the statute is "silent or ambiguous with respect to the specific issue," then the court proceeds to the second step of *Chevron*. *Chevron*, 467 U.S. at 843. The court must determine whether the agency's response to the question at issue is reasonable and based on a permissible construction of the statute. *Id.* If the agency provides a reasonable interpretation of the statute, the court must defer to the agency's interpretation. *Am. Library Ass'n v. FCC*, 406 F.3d 689, 699 (D.C. Cir. 2005). The agency's interpretation need not be "the only possible interpretation,

nor even the interpretation deemed *most* reasonable by the courts." *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 218 (2009) (emphasis in original). Moreover, "a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency." *Chevron*, 467 U.S. at 844.

III. ANALYSIS

A. CMS did not violate the APA when it revised what it means for an entity to furnish DHS

1. *Chevron* Step 1: CMS' interpretation of when an entity furnishes DHS does not violate Congressional intent

As described above, under the Stark Law, "if a physician . . . has a financial relationship with an entity," then the physician cannot refer his or her Medicare patients to that entity for the "furnishing" of DHS. 42 U.S.C. § 1395nn(a)(1)(A). Since the 2001 Regulations, the term "entity" has been defined as any physician's sole practice, group of physicians, or other organization that "furnishes" DHS. 42 C.F.R. § 411.351 (2001). The 2001 Regulations determined, however, that only the billing entity "furnishes" DHS. Thus, as long as the hospital was doing the billing, physician-owners could refer patients to the joint venture that was operating under arrangements with the hospital. This changed in 2008 when CMS expanded what it meant to "furnish" DHS so that both the billing entity and the entity that performed DHS were deemed entities that "furnish" DHS under the Stark Law. *See supra* Part I.B.2.b.

Plaintiff CUI contends that CMS acted arbitrarily and capriciously by changing what it means to "furnish" DHS."[7] Pl.'s Mot. at 27. More specifically, Plaintiff asserts that, "an

[7] CUI advances two tangential arguments. First, CUI argues that the term "entity" should not be defined as an organization that "furnishes DHS." *See* Pl.'s Mot. at 28 (asserting that Congress did not provide any definition for "entity" in the Stark Law, much less a "functional" test). In 2001, CMS defined "entity" as an organization that "furnishes DHS." *See* 66 Fed. Reg. at 923-24. To the extent that CMS challenges that definition, Plaintiff CUI should have brought his APA claims within six years of the 2001 Regulations. *See James Madison Ltd. by Hecht v.*

examination of the entire Stark Act shows that CMS' current interpretation of 'furnishing' in the context of services done [by an organization working] 'under arrangements' [with a hospital] defies Congressional intent." Pl.'s Reply at 14. As support for this argument, Plaintiff CUI points to § 1395(e)(7) of the Stark Law and argues that the 2008 regulatory definition of "furnishing" DHS would render that section meaningless. *Id.* at 15-16.

In response, CMS argues that the 2008 Regulations merely apply the common meaning of the word "furnish," *i.e.*, to provide or supply. Def.'s Mot. at 17. CMS insists that "the agency's interpretation of furnishing fits seamlessly with the plain language of the [Stark Law]," and that the plain language of the statute is the best evidence of Congressional intent. Def.'s Reply at 9. Moreover, CMS argues that the Stark Law's objectives are advanced by its interpretation of "furnishing" DHS. *Id.* at 20. Finally, as will be elaborated below, CMS provides specific arguments challenging the relevance of § 1395(e)(7) in deciphering what it means "furnish" DHS. *Id.* at 10-14.

Under the *Chevron* framework, the Court must first determine whether Congress unambiguously determined in the statute what it means to "furnish" DHS. *See Natural Res. Def. Council*, 643 F.3d at 322. It is clear that the Stark Law does not expressly define the term "furnish." However, as CUI points out, "the absence of a statutory definition does not render a

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Ludwig, 82 F.3d 1085, 1094 (D.C. Cir. 1996) (holding that the APA "carries a six-year statute of limitations"). Accordingly, the Court denies CUI's argument as untimely. The Court does, however, consider CUI's APA claims regarding the regulatory revisions to the definition of "furnishing."

Second, CUI contends that the term "outpatient hospital services" should not be interpreted to include all procedures done "under arrangements." Pl.'s Mot. at 23; *see also* Pl.'s Reply at 21-22. In the 2001 Regulations, CMS defined "outpatient hospital services" to specifically include services provided "under arrangements," 42 C.F.R. § 411.351 (2001). Because the statute of limitations period has run for an APA claim against agency action which occurred in 2001, the Court also deems this argument untimely. *See James Madison Ltd. by Hecht*, 82 F.3d at 1094.

word ambiguous." *Natural Res. Def. Council v. EPA*, 489 F.3d 1364, 1373 (D.C. Cir. 2007). Instead, "the 'words of the statute should be read in context, the statute's place in the overall statutory scheme should be considered, and the problem Congress sought to solve should be taken into account' to determine whether Congress has foreclosed the agency's interpretation." *Id.* (quoting *PDK Labs Inc. v. DEA*, 362 F.3d 786, 796 (D.C. Cir. 2004)); *see also TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (noting that courts must construe the language of the statute so that "no clause, sentence, or word shall be superfluous, void, or insignificant" (internal quotations omitted)). With these principles in mind, the Court turns to consider whether subsection (e)(7) of the Stark Law is rendered meaningless under CMS' definition of the term "furnish."

a. Background on subsection (e)(7)

Subsection (e)(7) concerns an arrangement whereby a physician group practice and its physician-members receive remuneration from the hospital in exchange for providing services for hospital patients.[8] Put in the language of the Stark Law, this is a compensation arrangement between the hospital and the physician-members of the group practice who are providing "under arrangements" services on behalf of the hospital. *See* 42 U.S.C. § 1395nn(h)(1) (defining a "compensation arrangement" as "any arrangement involving any remuneration between a physician . . . and an entity"). As previously discussed, a compensation arrangement is a type of

[8] A group practice is specifically defined in the Stark Law and is not the same as a joint venture. *See* 42 U.S.C. §1395nn(h)(4) (defining group practice). Plaintiff CUI acknowledges the difference between a group practice and a joint venture and understands that the compensation arrangement exception at subsection (e)(7) does not apply to joint ventures. Pl.'s Reply at 18. As discussed in further detail below, CUI nevertheless maintains that subsection (e)(7) is relevant here because it shows that Congress intended for an "entity" under the Stark Law not to include the entity that *performed* DHS.

financial relationship that triggers the Stark Law's ban on physician self-referrals. Because the physician-members have a compensation arrangement with the hospital, the Stark Law forbids these physicians from referring their Medicare patients to the hospital for the "furnishing" of DHS—unless, of course, a statutory exemption for the compensation arrangement exists.

Subsection (e)(7) provides a compensation arrangement exemption for group practices. It states that, if certain conditions are met, the arrangements between the physician-members of a group practice and a hospital will not be considered a compensation arrangement triggering Stark Law scrutiny. *See* 42 U.S.C. § 1395nn(e)(7) (allowing pre-1989 "arrangement[s] between a hospital and a group under which [DHS] are provided by the group but are billed by the hospital," so long as certain criteria were met).

Subsection (e)(7) does not make any reference to or any exemption for an *ownership* relationship that may exist between the physician-members of the group practice and the entity that is furnishing DHS. Thus, if a physician-member had an ownership or investment interest in the hospital, this would have triggered the Stark Law's ban on physician self-referrals and required an exemption for an ownership relationship, separate from the exemption for the compensation arrangement relationship. *See* 42 U.S.C. § 1395nn(a)(2)(A)-(B) (describing two types of financial interests that trigger the ban on physician self-referrals: (1) a physician's ownership or investment interest in the entity providing DHS and (2) a compensation arrangement between the physician and the entity). However, in the preamble to the 2001 Regulations, CMS expressed its view that by enacting subsection (e)(7) and exempting the compensation arrangement relationship between the physician-members and the hospital from Stark Law scrutiny, Congress had also implied that that physician-members of a group practice

do not have an ownership or investment interest *in the hospital*. *See* 66 Fed. Reg. at 942. CMS explained:

> In [subsection (e)(7)], the Congress created a specific compensation exception for certain hospital services provided by physician groups "under arrangements." Since, by definition, all services protected under [subsection (e)(7)]—and the resources used to produce them—were "owned" by the physician groups, the Congress would not have created a protected compensation relationship unless it had first determined that these arrangements did not create a prohibited ownership or investment interest *in the hospitals*. Simply stated, the Congress would not have excepted these relationships from the compensation arrangement restriction, if they were prohibited as an ownership or investment interest.

Id. (emphasis added).

In 2008, when CMS proposed revising the term "furnish" to include the provision of DHS, commenters (including some urologists) took notice that such a change would essentially treat physicians working "under arrangements" as having an ownership interest in the entity providing services, *e.g.*, the group practice or joint venture. Commenters argued that changing the meaning of "furnish" to include the provision of DHS "was contrary to Congress's decision, and/or [CMS' decision, as noted in the preamble for the 2001 Regulations,] to treat an 'under arrangements' relationship as a compensation arrangement, rather than an ownership interest, between the parties." 73 Fed. Reg. at 48,725. According to these commenters, "Congress unequivocally decided that the physician's ownership interest in the 'under arrangements' service provider is not an ownership interest in an entity furnishing DHS services, and that the only financial arrangement that triggers the physician self-referral law is the service agreement between the hospital and the under arrangements service provider."[9] *Id.*

In response to these comments, CMS explained that it "disagree[d] that, in enacting [subsection (e)(7)], the Congress determined that ownership in the entity performing DHS under

[9] The Court notes that the commenters' use of the term "under arrangements service provider" represents an expansion of the language of subsection (e)(7), which refers only to "group practices."

arrangements is not ownership in a DHS entity." *Id.* CMS maintained that "there is no indication in either the text of [the Stark Law] or its legislative history that the Congress intended to except ownership interests in the entity performing the service on behalf of the hospital." *Id.* Instead, CMS asserted, "the language of [subsection (e)(7)] clearly says that a group practice will not have a prohibited compensation arrangement with a hospital, if certification conditions are met: it does not address whether a referring physician has a prohibited ownership interest in the entity performing the service." *Id.*

b. The parties' arguments & analysis

In the instant litigation, Plaintiff CUI reasserts the position advanced by the commenters in 2008. CUI argues that "[i]mplicit in the creation of [subsection (e)(7)] is that Congress viewed entities acting 'under arrangements' with hospitals as having a compensation arrangement with the entity furnishing DHS (*i.e.*, the hospital), rather than an ownership interest." Pl.'s Mot. at 16. According to CUI, if Congress intended to ban physician-members of a group practice from referring their Medicare patients to the group practice for DHS (as is the case under the 2008 regulatory definition of "furnishing"), then there would have been very little point in Congress granting a compensation arrangement exception for the relationship between the hospital and the "under arrangements" entity. *Id.* at 17. Like the commenters in 2008, Plaintiff maintains that Congress must not have intended for the physician's ownership interest in the "under arrangements" service provider (*i.e.*, the group practice or, in Plaintiff's case, the joint venture) to constitute an ownership interest in an entity furnishing DHS services. *Id.* at 17. Therefore, Plaintiff concludes, the agency's 2008 definition of an entity furnishing DHS contravenes the Stark Law.

In response, CMS observes that the statutory text of subsection (e)(7) "expressly refers to [DHS] 'furnished by the group under the arrangement,'" thereby supporting that Congress considered that the entity providing services under arrangements, and not just the hospital, could "furnish" DHS under the Stark Law. Def.'s Reply at 10. Additionally, CMS echoes its previously articulated position that "subsection (e)(7) only addresses the financial relationship between the group practice and the hospital," and "does not address the separate financial relationship between the group practice and its [physician-]members." *Id.* In sum, CMS argues that referrals from physicians to their group practices were not exempted in subsection (e)(7). *Id.* Further, CMS contends that subsection (e)(7) is not rendered meaningless by the new definition of "furnishing" because even if a physician-member is not allowed to refer his own patients to the group practice, a compensatory arrangement exemption like the one embodied in subsection (e)(7) might still prove valuable. For instance, the exemption would still be valuable where the physicians are mere employees (and not owners) of a group practice that is owned by the hospital or a non-profit corporation. *Id*. at 11. Similarly, CMS argues, subsection (e)(7) may exempt a group practice from Stark Law liability in situations where, although the physician-member is considered an owner, he or she qualifies under the Stark Law for a ownership prohibition exemption, as provided elsewhere in the statute. *Id.* (discussing the ownership prohibition exemption for rural providers codified at 42 U.S.C. § 1395nn(d)(2)).

The Court finds CMS' arguments are correct and that Plaintiff's argument tries to force into the subsection (e)(7) exception far more than the language of the exception will bear. As an initial matter, the language of subsection (e)(7) itself supports that the entity furnishing DHS is the group that provides those services. *See id*. § 1395nn(e)(7)(A)(iii) (indicating that the compensation arrangement exemption requires that "substantially all of [the DHS] furnished to

patients of the hospital are furnished by the group under the arrangement"). Moreover, subsection (e)(7) falls under the section of the Stark Law that deals exclusively with compensation arrangement exceptions, *see* 42 U.S.C. § 1395nn(e), and makes no mention of exempting any ownership relationships, *id.* § 1395nn(e)(7). Yet Plaintiff argues that the subsection unambiguously means that physician-members of a group practice would not be deemed to have an ownership interest in the group practice—an especially troubling position given that the ownership interest by physician-members in their group practice is precisely the type of financial relationship that concerned Congress when it passed the Stark Law. *See* 42 U.S.C. § 1395nn(a)(2)(A).

What CUI would have this Court do is read an extension into the exception that is simply not there, *i.e.* that because CMS previously interpreted subsection (e)(7) as providing that physician-members of a group practice do not have an ownership interest in the *hospital*, this Court should now extend CMS' statutory interpretation and hold that Congress also implicitly recognized that physician-members of a group do not have an ownership interest in their *group practice*. The Court declines to do so. CMS never commented in the 2001 preamble as to whether a forbidden ownership relationship exists between the physician-members and the *group practice*; instead, CMS limited its comments to the ownership relationship between the physician-members and the *hospital*. Moreover, CMS' previous interpretation of subsection (e)(7) is not binding at the *Chevron* step one stage. *Nat'l Ass'n of Mfrs. v. NLRB*, 846 F. Supp. 2d 34, 48 (D.D.C. 2012) (rejecting notion that "an agency's interpretation controls for the purpose of Chevron step one"). In sum, nothing in the Stark Law unambiguously forecloses the agency's decision to define "furnishing" DHS to include the provider of DHS.

2. *Chevron* step 2: CMS offers a reasonable interpretation of what it means for an entity to furnish DHS

Having found that the Stark Law does not unambiguously foreclose CMS' definition of an entity "furnishing" DHS, the Court proceeds to the second step of *Chevron* and asks whether the agency's definition is reasonable. *See Chevron*, 467 U.S. at 843. Plaintiff CUI argues that CMS defined "furnishing" in an "impermissibly vague" fashion. Pl.'s Reply at 18. According to CUI, the agency has "refused to provide any meaningful guidance in the [2008] Regulations on when it would view a physician-owned joint venture as performing services that would render the joint venture an entity 'furnishing DHS.'" *Id.* at 19.

In response, CMS asserts that its regulatory definition of "furnishing" is not vague, but rather defines "furnishing" of a service to mean the performance of that service. CMS notes that when promulgating the 2008 Regulations it explained that a service is considered "to have been 'performed' by a physician or physician organization if the physician or physician organization does the medical work for the service and could bill for the service."[10] Def.'s Reply at 15 (quoting 73 Fed. Reg. at 48726). CMS insists that it has simply used the plain language definition of the word "furnishing," whereby a physician-owned entity that "performs" DHS can reasonably be said to "furnish" DHS. Def.'s Mot. at 17.

At *Chevron* step two, the Court must determine whether CMS' definition of "furnishing" in the 2008 Regulations is based on a permissible construction of the statute and whether the agency's approach is "reasonable in practice"—*i.e.*, whether it does not undermine the statutory regime. *Apotex v. FDA*, 414 F. Supp. 2d 61, 72 (D.D.C. 2006). Once the Court makes such a determination, the agency's view governs, regardless of whether it is the best or the most

[10] CMS also contends that an agency does not violate the APA merely by promulgating a rule that is vague. *Id.* Because the Court finds that the agency's definition is not vague, the Court does not find it necessary to reach this additional argument.

reasonable interpretation. *Southeast Ala. Med. Ctr. v. Sebelius*, 572 F.3d 912, 918 (D.C. Cir. 2009) (citing *Entergy Corp.*, 556 U.S. at 218).

During the notice and comment period, commenters asked CMS to clarify what it meant when it proposed that an entity under the Stark Law would include any entity that "performs" DHS. 73 Fed. Reg. at 48,726. CMS replied that the term "perform" "should have its common meaning," noting that "[p]hysicians and other suppliers generally know when they have performed a service and when they are entitled to bill for it." *Id.* By way of example, CMS explained that it would consider a service to be "performed" by "a physician or physician organization service if the physician or physician organization does the medical work for the service and could bill for the service." *Id.* It would make no difference then if "the physician or organization has contracted with a hospital and that the hospital bills for the service instead." *Id*. Accordingly, CMS gave ample notice to interested parties that the term "furnishing" would be given its plain language meaning, *i.e.* to provide a service.

Furthermore, this plain language definition for "performing," as it applies to an entity furnishing DHS, furthers the goals of the Stark Law. According to the Congressional record, the Stark Law was passed to deal with the "problems stem[ming] from the fact a physician's objectivity in making referrals is threatened by" the physician's financial interests. 135 Cong. Rec. 2035 (1989). It targeted "referral schemes [that were] being disguised as legitimate business arrangements, most commonly as partnerships involving referring physicians." *Id.* CMS, however, found that physician-owners of joint ventures managed to avoid Stark Law liability because the agency's regulations treated only the hospital (*i.e.*, the billing organization) to be an "entity" under the law. 73 Fed. Reg. at 48,725. The agency explained the situation as follows:

> Congress has made a policy decision to disallow self-referrals involving an ownership or investment interest, except in a few specified instances. . . . [W]e fail to see why the Congress would have intended that the general prohibition on physician referrals to entities in which they have an ownership or investment interest could be circumvented merely by arranging for the service provider to reassign to another, for a fee, the right to receive Medicare payment.

73 Fed. Reg. at 48,724.

By changing what it meant to "furnish" DHS to include those physicians and organizations that were performing DHS, the Stark Law and its implementing regulations would prohibit physician self-referrals in situations where a joint venture was working "under arrangements" with a hospital. In other words, physician-owners of joint ventures could no longer refer their Medicare patients to the joint venture without meeting one of the ownership exceptions. This result advances the Stark Law's objective to take a physician's financial interest out of the equation when he or she is referring patients for DHS.[11] As such, CMS' interpretation of what it means to "furnish" DHS is reasonable and consistent with the statutory purpose. *Northpoint Tech., Ltd. v. FCC*, 412 F.3d 145, 151, 366 U.S. App. D.C. 363 (D.C. Cir. 2005) ("A 'reasonable' explanation of how an agency's interpretation serves the statute's objectives is the stuff of which a 'permissible' construction is made."); *Liberty Maritime Corp. v. United States*, 928 F.2d 413, 419 (D.C. Cir. 1991) (concluding that the agency's interpretation was reasonable as it was "fully consistent with the purposes of the Act"); *see also Appalachian Power Co. v. EPA*, 249 F.3d 1032, 1058 (D.C. Cir. 2001) ("the [agency's] interpretation controls so long as it is based upon a permissible construction of the statute").

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[11] Plaintiff CUI argues that changing the definition of "furnishing" does not advance the Stark Law's purposes because laser surgery and other urological procedures are not DHS under the Stark Law. Pl.'s Mot. at 29; Pl.'s Reply at 22. This is a reiteration of CUI's argument that these urological procedures, although conducted "under arrangements" do not constitute "outpatient hospital services," and should therefore not be considered DHS. *Id.* As noted above, however, the Court rejects this argument as untimely. *See supra* n.7.

B. CMS did not violate the APA when it prohibited per-click payments made in the context of physician self-referrals

The next issue raised by Plaintiff CUI involves CMS' rule change prohibiting a hospital from paying a joint venture on a "per-click" or per-use basis for the leasing of equipment and use of technical personnel. As discussed above, the Stark Law permits lease agreements between physicians and entities if the lease agreement meets specific requirements. 42 U.S.C. § 1395nn(e)(1). Among other things, the "rental charges over the term of the lease [cannot be] . . . determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties." 42 U.S.C. § 1395nn(e)(1)(iv) ("Clause IV"). The House Conference Report on the 1993 amendments to the Stark Law addressed the exception for lease agreements, explaining:

> 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 agreement.

H. Rep. No. 103-213, at 814 (1993) ("Conf. Rep.").

Based in part on this language, the 2001 Regulations allowed per-click lease payments made by the hospital to a physician-owned joint venture, even where the physician-owners were referring their own Medicare patients for DHS to the joint venture. *See* 66 Fed. Reg. at 876-78. However, in the 2008 Regulations, CMS prohibited per-click lease payments stemming from physician self-referrals. *See* 42 C.F.R. § 411.357(b)(4)(ii)(B) (prohibiting per-click payments "to the extent that such charges reflect services provided to patients referred between the parties"); *id.* § 411.357(l)(3)(ii); *id.* § 411.357(p)(1)(i)(B). According to CMS, such per-click lease payments were susceptible to abuse, and "led to overutilization, affected clinical decision-

making, and resulted in an anti-competitive market for the rental of hospital equipment." 73 Fed. Reg. at 48,713-14. CMS promulgated these regulatory changes pursuant to the Secretary's statutory power to "impose by regulation" any "other requirements . . . as needed to protect against [Medicare] program or patient abuse." 42 U.S.C. § 1395nn(e)(1)(A)(vi); *id.* § 1395nn(e)(1)(B)(vi).

Plaintiff challenges these regulatory changes, arguing that the 2008 Regulations violate Congress' intent to allow per-click payments and that CMS acted arbitrarily and capriciously in making these changes.

1. *Chevron* Step 1: Congress did not unambiguously state its intention to protect per-click payment arrangements

Pointing to the Conference Report, Plaintiff CUI argues that Congress expressly permitted per-click payments as long as the payment rate did not fluctuate based on the volume of referrals. Pl.'s Mot. at 16. CUI contends that CMS did not have "the power to override congressional intent," notwithstanding that the Stark Law gives CMS the authority to add conditions to compensation arrangement exceptions. *Id.* at 18.

Defendant CMS counters that when it prohibited per-click payments in the context of physician self-referrals, it was acting under the Secretary's statutory authority to "impose 'other requirements' beyond those established by [C]ongress for a lease to qualify for a compensation exception." Def.'s Mot. at 30. CMS argues that neither the Stark Law's text nor its legislative history restricts the agency's authority to impose such "other requirements," and in no way require the allowance of per-click payments. *Id.* According to CMS, even if Congress did not think that . . . per-click payments ran afoul" of the statutory conditions exempting lease arrangements from the Stark Law, this in no way diminishes the Secretary's authority to impose further restrictions on per-click lease arrangements if she determines that it is needed to protect

against Medicare program or patient abuse. *Id.* at 35. CMS explains that "[t]he whole point of [the Secretary's statutory authority] in the leasing exceptions is to give the Secretary the power to impose additional restrictions beyond those expressly [included] by Congress," assuming the restrictions are warranted to protect against abuse of the Medicare program or patients. *Id.*

Under *Chevron* step one, the Court must determine whether Congress unambiguously expressed its intent to allow per-click payments under the Stark Law and limit the Secretary's power to impose additional restrictions on lease arrangements. *See Natural Res. Def. Council v. Envt'l Prot. Agency*, 706 F.3d 428, 431 (D.C. Cir. 2013) (explaining that the Court must first ask "whether Congress has directly spoken to the precise question at issue, in which case [the Court] must give effect to the unambiguously expressed intent of Congress" (quoting *Chevron*, 467 U.S. at 842-43)). "As [the Supreme Court] has repeatedly held, the authoritative statement [when interpreting a statute] is the statutory text, not the legislative history or any other extrinsic material. Extrinsic materials have a role in statutory interpretation only to the extent they shed a reliable light on the enacting Legislature's understanding of otherwise ambiguous terms."[12] *Exxon Mobil Corp. v. Allapattah Servs.*, 545 U.S. 546, 568 (2005). Thus, to be relevant, the legislative history must be "anchored" to ambiguous statutory text. *Shannon v. United States*, 512 U.S. 573, 584 (1994). Congressional intent on an issue cannot be gleaned from a statute's legislative history—no matter how direct that intent may be voiced—if the statutory text makes no reference to that issue in the first place. *See Int'l Bhd. of Elec. Workers v. NLRB*, 814 F.2d

[12] "As a general matter, 'it is the statute, and not the Committee Report, which is the authoritative expression of the law.'" *United States v. Opportunity Fund (In re Any & All Funds Or Other Assets, in Brown Bros. Harriman & Co.)*, 613 F.3d 1122, 1129 (D.C. Cir. 2010) (internal quotations omitted). The Supreme Court has explained that "judicial reliance on legislative materials like committee reports, which are not themselves subject to the requirements of Article I, may give unrepresentative committee members—or, worse yet, unelected staffers and lobbyists—both the power and the incentive to attempt strategic manipulations of legislative history to secure results they were unable to achieve through the statutory text." *Exxon Mobil Corp. v. Allapattah Servs.*, 545 U.S. 546, 568 (2005).

697, 712 (D.C. Cir. 1987) ("[A] cardinal principle of the judicial function of statutory interpretation is that courts have no authority to enforce principles gleaned solely from legislative history that has no statutory reference point.").

Here, Plaintiff CUI presents the Conference Report as evidence that Congress intended to allow "per-click" payments, even in the context of physician self-referrals. However, for this piece of legislative history to play an authoritative role in construing the Stark Law, CUI would have to point to some ambiguous statutory language suggesting that "per-click" payments should always be permitted. In other words, the Conference Report would have to shed light on otherwise ambiguous statutory terms. Yet CUI has not pointed the Court to any statutory language in the Stark Law that remotely suggests that per-click payments must be allowed unconditionally. Indeed, the Stark Law contains no language—not even ambiguous language—permitting lease payments calculated according to units of service.

Plaintiffs would presumably argue that the Conference Report can be said to interpret Clause IV, which requires that lease agreements for space or equipment not be "determined in a manner that takes into account the volume or value of any referrals." 42 U.S.C. § 1395nn(e)(1)(iv). Arguably, Clause IV is ambiguous because it can be interpreted as *prohibiting* per-click leases. Thus, the Conference Report might help clarify whether Congress intended that per-click leases be prohibited under Clause IV. However, this Court is not being asked whether Congress intended that per-click leases be prohibited under Clause IV: CMS does not rely on Clause IV to support its prohibition on per-click payments in the context of physician self-referrals, but rather relies on the Secretary's statutory authority to impose "other requirements" under 42 U.S.C. § 1395nn(e)(1)(vi). By its plain text, Clause IV does not, either ambiguously or

unambiguously, require that per-click payments always be permitted, and, therefore, does not limit the Secretary's statutory authority to impose "other requirements."

In sum, the Conference Report's utility can "extend no further than the light it sheds on how the enacting Legislature understood the statutory text." *Exxon Mobil Corp.*, 545 U.S. at 570. Because the language of the Stark Law makes no comment, ambiguous or not, on whether "per-click" payments must be permitted, the challenged 2008 Regulations do not fail under *Chevron* step one. *See Petit v. U.S. Dep't of Ed.*, 675 F.3d 769, 781 (D.C. Cir. 2012) (explaining that to prevail at Chevron step one, the plaintiff "must show that the statute unambiguously forecloses the agency's interpretation" or, "put another way, they must demonstrate that the challenged term is susceptible of only one possible interpretation" (internal citations omitted)). At most, this is a case where Congress decided to tackle an issue through the legislative history that, for whatever reason, it did not treat in the statutory text. Under such circumstances, the legislative history is of no use whatsoever. *See ExxonMobil Gas Marketing Co. v. Federal Energy Regulatory Commission*, 297 F.3d 1071 (D.C. Cir. 2002) (holding that "snippets of legislative history do not make law"); *In re Sealed Case*, 237 F.3d 657, 669 (D.C. Cir. 2001) ("The limits on the [agency's] authority—like that authority itself—are derived from statutory provisions, not from loosely worded fragments extracted from congressional reports and speeches."). Accordingly, the Court moves on to step two of the *Chevron* analysis. *Ala. Educ. Ass'n v. Chao*, 455 F.3d 386, 392 (D.C. Cir. 2006) (explaining that when a statute is silent or ambiguous on the pertinent issue, the court moves on to step 2 of *Chevron*).

2. *Chevron* Step 2: CMS has reasonably interpreted the Stark Law to allow restrictions on per-click payments in the context of physician self-referrals

At *Chevron* step two, the Court asks "whether the agency has reasonably explained how the permissible interpretation it chose is 'rationally related to the goals of the statute.'" *Petit v. U.S. Dep't of Ed.*, 675 F.3d at 785 (citations omitted). As discussed above, prior to the 2008 Regulations, CMS permitted the hospital to make per-click lease payments to a physician-owned joint venture, even when the physician-owners were referring their own Medicare patients for DHS to the joint venture. 66 Fed. Reg. at 876 (allowing per-click payments "even when the physician receiving the payment has generated the payment through a DHS referral"). CMS believed that the Conference Report showed Congress had intended to "protect" per-click payments, "so long as the payment 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." *Id.* However, in the 2008 Regulations, CMS changed course and prohibited per-click payments in the context of physician self-referrals. 73 Fed. Reg. at 48,713 (deciding to "prohibit per-click payments to physician lessors for services rendered to patients who were referred by the physician lessor"). CMS promulgated the revised regulations pursuant to the Secretary's authority to impose any further requirements for lease agreements that are "needed to protect against program or patient abuse." *Id.*; *see also* 42 U.S.C. §§ 1395nn(e)(1)(A)(vi) and 1395nn(e)(1)(B)(vi).

Plaintiff CUI claims that CMS violated the APA by not providing a reasoned analysis as to why it changed its position on the permissibility of per-click payments under the Stark Law. Pl.'s Mot. at 17. Furthermore, CUI argues that CMS acted improperly under the Secretary's statutory authority to impose additional restrictions because there is no empirical evidence that

per-click payments for laser surgery or other urological procedures lead to patient abuse or harm to the Medicare system.[13] *Id.* at 19.

Defendant CMS asserts in response that when "a physician lessor has the opportunity to be paid per-click for referrals that she makes for the use of her own equipment," this creates an economic incentive to overutilize a certain course of treatment. Def.'s Mot. at 37. According to CMS, it was the existence of such an economic incentive that led the Secretary to promulgate the new regulation banning certain per-click leases. *Id.* CMS argues that the Secretary was "not required to wait until there [was] extensive evidence of program or patient abuse, but instead [could] act prophylactically to prevent such abuses from occurring where, as here, the Secretary determines based on her expertise and experience that [additional lease arrangement requirements], are 'needed' to protect the Medicare program or patients." *Id.* at 39.

"'An agency's interpretation of a statute is entitled to no less deference simply because it has changed over time.' Rather, the question raised by the change is whether the Department has supported its new reading of [the statute] with a 'reasoned analysis' sufficient to command [the Court's] deference under *Chevron*." *Ala. Educ. Ass'n v. Chao*, 455 F.3d 386, 396 (D.C. Cir.

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[13] CUI also contends that CMS acted arbitrarily by allowing per-click payment arrangements for procedures done in an Ambulatory Surgical Center or a physician's office, while not allowing per-click payments for "procedures done in hospitals by physician-owned entities where the physicians treat their own patients." Pl.'s Mot. at 22. CMS responds that procedures done in Ambulatory Surgical Centers or a physician's office are not considered DHS under the Stark Law, and, therefore, are not subject to the Stark Law's prohibitions on physician self-referrals. Def.'s Mot. at 37-38. Indeed, under the Stark Law, procedures done in hospitals by physician-owned entities are "outpatient" services, and, therefore, are considered DHS. *See* 42 U.S.C. § 1395nn(h)(6) (listing the services considered DHS). Meanwhile, Congress did not prescribe that procedures done at Ambulatory Surgical Center and physician's office were DHS, and, therefore, these procedures do not trigger Stark Law scrutiny. *Id.* Accordingly, it makes sense that CMS would allow per-click payment arrangements for procedures done in an Ambulatory Surgical Center or a physician's office because such procedures are not under the province of the Stark Law. To the extent that CUI is arguing that procedures done in hospitals by physician-owned entities should not be considered "outpatient" services (or, for that matter, that services performed in Ambulatory Surgical Center or in a physician's office should be considered "outpatient" services), the Court has already rejected this argument as untimely. *See supra* n.7.

2006) (quoting *Nat'l Home Equity Mortgage Ass'n v. Office of Thrift Supervision*, 373 F.3d 1355 (D.C. Cir. 2004)). As the Supreme Court explained in *Chevron* itself,

> The fact that the agency has from time to time changed its interpretation of [the statute at issue] does not . . . lead us to conclude that no deference should be accorded the agency's interpretation of the statute. An initial agency interpretation is not instantly carved in stone. On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis.

Chevron, 467 U.S. at 863-64. Accordingly, the proper inquiry for the Court is whether CMS has provided a reasoned analysis for the Secretary's recent interpretation that the Stark Law permits prohibiting per-click payments in the context of physician self-referrals, and that such prohibition furthers the goals of the Stark Law.

CMS explained that "upon further analysis of the legislative history, [it] no longer believe[d] that the interpretation [it had previously] adopted . . . [was] the only reasonable interpretation of the statute and legislative history."[14] 73 Fed. Reg. at 48,713. More important, however, CMS went on to analyze how the Stark Law's purpose was furthered by the 2008 Regulations' restrictions on per-click payments. CMS expressed its ongoing concern that per-click payment arrangements for leases were "susceptible to abuse," citing to the commenters' experiences who had written to support the new regulations. *Id.* at 48,714.

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[14] In a *Chevron* step two analysis, the Court's focus is not on whether the agency can successfully reconcile its past position with its current position. "An agency is not required to establish 'rules of conduct to last forever,' but rather 'must be given ample latitude to adapt its rules and policies to the demands of changing circumstances." *United States Air Tour Ass'n v. FAA*, 298 F.3d 997, 1006 (D.C. Cir. 2002) (quoting State Farm, 463 U.S. at 42). Thus, the agency remains free to reinterpret a statute in a way that varies greatly from its past interpretation so long as the agency provides a reasoned basis for its new interpretation. *See Chevron*, 467 U.S. at 863 (explaining that "[a]n initial agency interpretation is not instantly carved in stone"). All that CMS must do to pass *Chevron* step two muster is provide a reasoned analysis for its new understanding that the Stark Law allows the Secretary to prohibit per-click payments in the context of physician self-referrals. *See Ala. Educ. Ass'n v. Chao*, 455 F.3d 386, 396 (D.C. Cir. 2006). CMS does not need to explain how the Conference Report (which this Court has already explained is not legally authoritative) fits into its new understanding of the Stark Law, so long as CMS has a reasoned analysis for its new interpretation of the Stark Law.

These commenters believed "that some leasing arrangements are abusive and provide incentives to physicians to narrow their choice of treatment options to those for which they will realize a profit." *Id.* Moreover, they expressed that

> Financial motivation is driving treatment choices (that is, whereas options exist for the treatment of diseases, physician ownership of equipment plays a key role in influencing what the patient ultimately will be prescribed); physicians sometimes steer patients to facilities that are willing to lease equipment from the physicians; overutilization is created by practices that, due to physician ownership, use treatments that yield lower efficacy outcomes and causes the need for re-treatment; and, physicians pressure hospitals to use their leasing company despite not being the low cost provider.

Id. One employee of a laser company claims that he witnessed "gross abuses of the current physician self-referral law, following the proliferation of urologist-owned LLCs." *Id.* Such "abuses" included

> [p]hysicians threatening hospitals into using the physician's company; hospitals violating contracts because they believe that the consequences of a broken contract will be less severe than not letting the physician have his or her way; and physicians steering patients to equipment they own, rather than use a third party for which the hospital has contracted, even if it means having the patient travel to a non-convenient hospital.

Id. at 48,714. Another commenter, an individual who ran a business leasing lasers for urological procedures, "stated that his company has obtained new technology lasers that offer improved clinical results and other benefits to patients, but that his company sometimes has difficulties in persuading physicians to allow the newer technology lasers to be brought into a hospital because the physicians have no ownership in the equipment." *Id.* Finally, CMS noted that past studies had "consistently found that physicians who had financial relationships with entities to which they referred ordered more services than physicians without such financial relationships." *Id.* at 48, 716 (citing 63 Fed. Reg. at 1661). Such evidence of "overutilization and anti-competitive

behavior" persuaded CMS "that the lease exceptions need[ed] to be modified . . . to address a burgeoning risk of abuse and increased costs to the Medicare program." *Id.* at 48,716. Thus, contrary to Plaintiff CUI's assertions, CMS did indeed rely on evidence that per-click payments lead to patient abuse or harm to the Medicare system in the context of physician self-referrals.[15]

Moreover, in modifying the lease exception with the 2008 Regulations, CMS highlighted that the "clear, overarching purpose of the [Stark Law]" was to protect the Medicare system and its recipients by preventing physician's financial relationships from affecting "utilization, patient choice, and competition." 73 Fed. Reg. at 48,716. CMS explained that the Stark Law was meant to respond to meet these goals while also maintaining flexibility to adapt to "the changing circumstances and developments in the health care industry." *Id.* Reflecting that flexibility, Congress "included the means to address evolving fraud risks by inserting into many of its exceptions . . . specific authority for the Secretary to add conditions as needed to protect against abuse." *Id.* Giving the Secretary the statutory authority to promulgate new regulations that prohibit per-click payments in the context of physician self-referrals effectuates these goals. Having provided a reasoned analysis, the Court must defer to CMS' interpretation of the Secretary's statutory authority, as codified at 42 U.S.C. §§ 1395nn(e)(1)(A)(vi) and 1395nn(e)(1)(B)(vi). *See Petit*, 675 F.3d at 785 (noting that deference is required if an agency has "reasonably explained how the permissible interpretation it chose is rationally related to the goals of the statute") (internal quotations omitted).

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[15] CUI suggests that CMS' evidence is insufficient, either in quality or quantity. However, Congress did not explicitly require, in its grant of statutory authority to the Secretary that she clear a specific evidentiary hurdle prior to imposing additional restrictions for lease exceptions. If Congress had wanted the Secretary to meet a specific evidentiary burden of proof, it would have said so. Because Congress did not include any such burden, it remains within the agency's discretion to draw conclusions from these comments, especially given that this is precisely the type of issue which rests within the expertise of CMS and "upon which a reviewing court must be most hesitant to intrude." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 53 (1983).

C. CMS did not violate the Regulatory Flexibility Act

Plaintiff CUI argues that CMS failed to provide a regulatory flexibility analysis as required under the RFA. Pl.'s Mot. at 32. Instead, CUI contends that CMS "simply assumed that the Regulations would not have a significant economic impact on a substantial number of small entities." *Id.* As relief, CUI urges the Court to invalidate the challenged regulations. *Id.* at 34.

Defendant CMS responds that the regulatory flexibility analysis for the challenged regulations, like the challenged regulations themselves, were part of a much larger rulemaking entitled "Inpatient Prospective Payment System." Def.'s Mot. at 42. According to CMS, the regulatory flexibility analysis that was provided for the larger rulemaking satisfies the RFA requirement, as it incorporates by reference the agency's analysis as discussed throughout the preamble to the 2008 Regulations. *Id.* Additionally, CMS contends that when it enacted the challenged regulations, CMS also certified that it did not anticipate the challenged regulations to have a significant impact on physicians, health care providers and suppliers, or the Medicare or Medicaid programs and their beneficiaries. *Id.* CMS insists that "[b]ecause of this certification, the agency was not required to prepare a final regulatory flexibility analysis that specifically discussed the impact of its per-click or under arrangements rules on small business." *Id.*

"When promulgating a rule, an agency must perform an analysis of the impact of the rule on small businesses, or certify, with support, that the regulation will not have a significant economic impact on them." *Nat'l Mining Ass'n v. MSHA*, 512 F.3d 696, 701 (D.C. Cir. 2008). Section 604(a) sets forth the specific items that must be included in a final regulatory flexibility analysis. 5 U.S.C. § 604(a)(1)-(7). However, an agency does not need to meet the requirements listed in § 604, "if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'" *Aeronautical Repair*

Station Ass'n v. FAA, 494 F.3d 161, 175 (D.C. Cir. 2007) (quoting 5 U.S.C. § 605(b)). Such a certification must be published in the Federal Register, along with a statement providing the factual basis for such certification. 5 U.S.C. § 605(b).

As CMS notes, the 2008 Regulations at issue were promulgated as part of a final rule entitled "Inpatient Prospective Payment System" ("IPPS"). CMS issued a Regulatory Impact Analysis for the final rule, wherein it discussed the "Effects of Policy Changes Relating to Physician Self-Referral Provisions," and, specifically, the regulatory changes for per-click payments in lease arrangements and services provided "under arrangements." 73 Fed. Reg. at 49,077. There, CMS stated that it does "not anticipate that these final policies [relating to physician self-referral provisions] will have a significant impact on physicians, other health care providers and suppliers, or the Medicare or Medicaid program and their beneficiaries." *Id.* As the factual basis for this certification, CMS points to its preamble for the 2008 Regulations, which it expressly incorporated as part of the impact analysis. According to CMS, the preamble supports that it was unlikely that small entities would be significantly impacted by the challenged regulations because "physician-owned entities would be able to continue existing arrangements based on referrals from non-physician owners and that these entities could potentially restructure existing lease arrangements to comply with the Secretary's regulations." Def.'s Mot. at 43. Additionally, CMS contends that the impact would be lessened by the fact that the agency delayed the effective date of the challenged regulations, precisely to give physician-owned entities and hospitals time to restructure their existing contracts. *Id.*

Plaintiff provides no argument in response. *See generally* Pl.'s Reply. Accordingly, the Court shall exercise its discretion to treat as conceded CMS' argument that it adequately complied with the certification requirements of 5 U.S.C. § 605(b), and that, therefore, the agency

did not have to provide any additional final impact analysis for the challenged regulations. *Hopkins v. Women's Div.*, 284 F. Supp. 2d 15, 25 (D.D.C. 2003) ("It is well understood in this Circuit that when a plaintiff files an opposition to a dispositive motion and addresses only certain arguments raised by the defendant, a court may treat those arguments that the plaintiff failed to address as conceded.").

IV. CONCLUSION

For the foregoing reasons, the Court denies Plaintiff's motion for summary judgment and grants Defendant's cross-motion for summary judgment.

May 24, 2013

BARBARA J. ROTHSTEIN
UNITED STATES DISTRICT JUDGE