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OFFICIAL MAGAZINE OF AMERICAN HEALTH LAWYERS ASSOCIATION

Dear CMS: We'd Like Our Rabbit Back

The Case for Reinstating the Stark Law's Physician Payments Exception

By Chris Janney, Gadi Weinreich, and Caroline Reigart, Dentons

The federal physician self-referral statute[1] and its implementing regulations[2]—commonly referred to as the "Stark Law"—has become an increasingly favored tool for combatting health care fraud and abuse. Although there are a host of reasons for this trend, four stand out. First, unlike most anti-inducement statutes, the Stark Law has no scienter requirement—it can be violated whether the parties intend to do so or not. Second, the Stark Law is a classic example of an overinclusive statute; that is, it presumes that a large swath of conduct is illegal, and then provides for scores of exceptions, at least one of which must be met in order to rebut this presumption. Third, many of the Stark Law's exceptions have a large number of requirements, are complicated, or both. Fourth, a violation of the Stark Law may give rise to a violation of the federal civil False Claims Act (FCA),[3] and FCA actions can be brought by the federal government or private citizens (whistleblowers) and can result in enormous liability. Under these circumstances, any effort by federal regulators to eliminate a Stark Law exception—particularly one created by statute—is cause for concern. This article examines such an effort.

The Stark Law generally prohibits a physician from referring a Medicare beneficiary to a health care provider for the furnishing of certain so-called "designated health care services" (DHS) if the physician (or an immediate family member of the physician) has a financial relationship with the provider (DHS Entity).[4] (DHS include, by way of example, hospital inpatient and outpatient services and clinical laboratory services.)[5] The Stark Law also prohibits the DHS Entity from billing Medicare (or any other person or entity) for services furnished pursuant to such a referral.[6] Because the term "financial relationship" is defined broadly[7]—to include any arrangement pursuant to which a physician and DHS Entity exchange "remuneration"[8]—the Stark Law arguably prohibits most physicians from referring *any* Medicare beneficiary to *any* hospital, laboratory, or other DHS Entity. To wit:

- "remuneration" is essentially anything of value,
- donuts are "remuneration,"
- therefore, when a hospital leaves a tray of donuts in the physicians' lounge and Dr. Jones takes one—presto!—the hospital and Dr. Jones have a "financial relationship" in the form of a direct compensation arrangement and Dr. Jones can no longer refer Medicare patients to the hospital and, if she does, the hospital cannot bill for any services furnished to those patients.

To its credit, Congress recognized the overbreadth of the Stark Law's underlying prohibitions and during the first four years following its passage (1989–1993) created a number of statutory exceptions to its prohibitions.[9] In enacting the Stark Law, Congress was mostly concerned with *DHS Entities* providing something of value to *physicians* to influence their referral decisions. Indeed the raison d'etre for the Stark Law were studies showing that physicians with an ownership interest in clinical laboratories ordered more lab tests than physicians who did not have such ownership interests.[10]

Not surprisingly, then, most of the statutory exceptions created by Congress address arrangements pursuant to which the *DHS Entity* is paying the *physician* (and not vice versa). For example, Congress created an exception that protects compensation a DHS Entity pays to physician-employees, provided certain conditions are satisfied (Employment Exception).[11] A similar exception protects compensation a DHS Entity pays to physician-contractors, again provided certain conditions are satisfied (Personal Services Exception).[12]

Congress also recognized that, at least on occasion, an arrangement might involve a *physician* paying a *DHS Entity* for an item or service. For example, a physician practice might obtain certain administrative services from a hospital, or a physician might purchase something from the hospital's gift shop or cafeteria. To address these scenarios, Congress enacted the so-called "payments by a physician exception" (Physician Payments Exception).[13] By its terms, this exception is both broad and straightforward, essentially protecting any amount that a physician pays to a DHS entity for "items or services" as long as the payment is "consistent with fair market value." More specifically, the exception protects "[p]ayments made by a physician" either (1) to "a laboratory in exchange for the provision of clinical laboratory services," or (2) to any entity "as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value."[14]

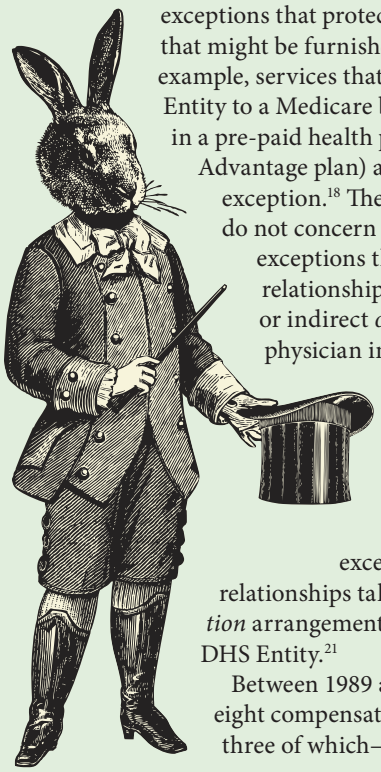
The differences between the Physician Payments Exception, which protects payments by a physician to a DHS Entity, and the Personal Services Exception, which protects payments by a DHS Entity to a physician, are striking. As noted, where a physician pays a DHS Entity for services, the physician Payments Exception applies as long as the physician's payment is consistent with fair market value. By contrast, where it is the DHS Entity that pays a physician for services, the requirements of the Personal Services Exception are numerous and onerous.

Among other things, the arrangement between the DHS Entity and physician must (1) be "set out in writing," (2) be "signed by the parties," (3) "specif[y] the services covered by the arrangement," (4) cover "all of the services to be provided by the physician" to the entity, and (5) have a term of at least one year.[15] In addition, the compensation to be paid by the DHS Entity to the physician "over the term of the arrangement" must be "set in advance," (7) must "not exceed fair market value," and (8) must not be determined in a manner that takes into account the volume or value of the physician's referrals to or other business generated for the DHS Entity.[16]

Plainly then, Congress was much more concerned about DHS Entities paying physicians for services than vice versa. Notwithstanding this clear legislative intent, however, in a series of rulemakings between 1995 and 2007, the Centers for Medicare & Medicaid Services (CMS) and its predecessor, the Health Care Finance Administration (HCFA), have taken the position that the *statutory* Physician Payments Exception is so narrow as to be, effectively, null and void. That is, its plain language notwithstanding, CMS has interpreted the exception to *not* protect arrangements pursuant to which a physician pays a DHS Entity fair market value for services. How this particular rabbit got into this particular hat—and how we might rescue it—is the subject of this article.

Congress and the Stark Law

As noted, when Congress enacted the Stark Law in 1989, it realized a number of exceptions to its broad referral and billing prohibitions would be necessary. To that end, Congress created three categories of exceptions. First, there are exceptions that protect certain types of *services* that might be furnished by a DHS Entity.[17] For example, services that are furnished by a DHS Entity to a Medicare beneficiary who is enrolled in a pre-paid health plan (e.g., a Medicare Advantage plan) are protected by one such exception.[18] These service-based exceptions do not concern us here. Second, there are exceptions that that protect financial relationships taking the form of direct or indirect *ownership* interests by a physician in a DHS entity,[19] such as a physician's ownership of stock in a hospital.[20] These ownership exceptions also do not concern us here. Third, and of relevance to this article, there are exceptions that protect financial relationships taking the form of *compensation* arrangements between a physician and DHS Entity.[21]



Between 1989 and 1993, Congress created eight compensation arrangement exceptions, three of which—the Employment Exception, the Personal Services Exception, and the Physician Payments Exception—we've touched on briefly above. The other five exceptions are as follows:

Congress also recognized that, at least on occasion, an arrangement might involve a *physician* paying a *DHS Entity* for an item or service.

- **Space & Equipment Rental Exception.**[22] Provided a number of conditions are satisfied, this exception protects arrangements whereby (1) a DHS Entity leases space or equipment to a physician or (2) a physician leases space or equipment to a DHS Entity. This exception is an example of a "two-way" exception; that is, it protects payments running from a DHS Entity to a physician, and from a physician to a DHS Entity (DHS Entity ↔ Physician). The exception does not, however, protect services arrangements. Thus, this exception would not protect a physician's payment to a DHS Entity for services.
- **Isolated Transactions Exception**.[23] Provided a number of conditions are satisfied, this exception protects "isolated financial transactions, such as a one-time sale of property or practice." Like the Space & Equipment Rental Exception, this exception is a two-way exception (DHS Entity ↔ Physician), protecting arrangements whereby (1) a DHS Entity purchases property or some other asset from a physician (2) or a physician purchases property or some other asset from a DHS Entity. Also like the Space & Equipment Rental exception, this exception would not appear to protect traditional services arrangements and, as such, would not protect a physician's payment to a DHS Entity for services.
- **Physician Recruitment Exception**.[24] Provided a number of conditions are satisfied, this exception protects compensation from a hospital to a physician to induce him or her to relocate to the hospital's geographic service area. This exception is a "one-way" exception; that is, it only protects compensation flowing from a DHS Entity to a physician (DHS Entity → Physician), and not vice versa. Thus, this exception would not protect a physician's payment to a DHS Entity for services.
- **Hospital Group Practice Exception**.[25] Provided a number of conditions are satisfied, this exception protects certain arrangements between a hospital and a physician group "under which designated health services are provided by the group."[26] Once again, this exception only protects compensation flowing from the DHS Entity to the physician (DHS Entity → Physician), and not vice versa. Thus, this exception would not protect a physician's payment to a DHS Entity for services.
- **Unrelated to DHS Exception**.[27] This exception protects "remuneration which is provided by a hospital to a physician if such remuneration does not relate to the provision

of designated health services."[28] Once again, this exception only protects compensation flowing from the DHS Entity to the physician (DHS Entity → Physician). Thus, this exception would not protect a physician's payment to a DHS Entity for services.

In sum, of the eight compensation arrangement exceptions that Congress created between 1989 and 1993, only one—the Physician Payments Exception—protects arrangements whereby a physician pays a DHS Entity for services. That Exception in turn is unequivocal: it protects *any* payments made by any physician to (1) a clinical laboratory for laboratory services or (2) any DHS Entity for any other (i.e., non-laboratory) services, as long as the payment for the services is consistent with fair market value.

Since 1993, Congress has not created any additional compensation arrangement exceptions. However, the Stark Law expressly permits CMS to create additional regulatory exceptions where it determines doing so will not pose a risk of program or patient abuse,[29] and utilizing this authority, CMS has created two dozen additional regulatory exceptions. In addition to creating new regulatory exceptions, six of the eight statutory compensation arrangement exceptions allow CMS to establish additional conditions that must be satisfied in order for those exceptions to be met.[30] Pursuant to this statutory authorization, CMS has made modifications to the conditions of each of these six exceptions.[31]

Importantly, although the Stark Law permits CMS to create new regulatory exceptions, it does not permit CMS to eliminate existing statutory exceptions. Further, although the Stark Law permits CMS to add new conditions to a number of the eight statutory compensation arrangement exceptions, the Physician Payments Exception is not among them. Simply put, Congress did not authorize CMS to *eliminate* or *modify* the Physician Payments Exception. Notwithstanding, that is exactly what CMS has done.

HCFA/CMS and the Stark Law

The Hat

HCFA made its first substantial foray into Stark Law rulemaking in 1995, six years after the Stark Law was enacted. In that rulemaking, HCFA created a regulatory Physician Payments Exception, codified at 42 C.F.R. § 411.357(i).[32] The regulatory text essentially mirrored the statutory exception, codified at section 1877(e)(8) of the Social Security Act.[33] In addition, the agency confirmed—repeatedly—that the Physician Payments Exception meant exactly what it said:

- Could a physician hire a laboratory to furnish "waste transport" services? Yes: "if a physician is paying fair market value to the supplier entity for whatever nonlaboratory services he or she is purchasing, referrals by the physician to the laboratory should not be prohibited. However, the arrangement must meet the conditions found in" the Physician Payments Exception.[34]
- Could a physician hire a laboratory to furnish "educational" services? Yes: the Physician Payments Exception "allows a physician to make payments to any entity (including a laboratory) for items and services, other than clinical laboratory services, if the purchase is consistent with fair market value."[35]
- Could a physician hire a laboratory to furnish "management" services? Yes: the Physician Payments Exception protects "payments by a physician to an entity in exchange for items or services other than clinical laboratory services."[36]
- Could a physician hire a DHS Entity to serve as a "clinical" or "technical" consultant? Yes: the Physician Payments Exception protects "physicians who contract with an entity outside of their office for items or services, providing the items or services are furnished at a price that is consistent with fair market value."[37]
- Finally, a commenter asked if HFCA would "add a new exception to the prohibition on referrals to address certain compensation arrangements in which a physician pays a reasonable fee to a laboratory to provide a service in an area in which the physician or his or her office personnel lack expertise." No: "an additional exception… is not necessary." The Physician Payments Exception already protects "payments made by a physician to any entity as compensation for items and services (other than clinical laboratory services) if the items or services are priced at fair market value."[38]

The Rabbit

In the years following HCFA's 1995 rulemaking, a number of health care organizations and trade associations complained that HCFA had not gone far enough in creating exceptions to protect financial relationships. These commenters noted, for example, that whereas the Physician Payments Exception protected any arrangement whereby a physician purchased items *or* services from a DHS Entity, the Personal Services Exception only protected arrangements whereby a DHS Entity purchased *services* from a physician.[39] In response to these industry comments, HCFA proposed several new regulatory exceptions in 1998, including a "fair market value compensation" exception (FMV Exception).[40] Like the Personal Services Exception, the proposed FMV Exception would only protect arrangements pursuant to which the DHS Entity compensated the physician. Unlike the Personal Services Exception, however, the FMV Exception would protect any arrangement whereby a DHS Entity compensated a physician for items *or* services.[41]

In short, the Physician Payments and (proposed) FMV Exceptions were mirror images, each protecting exchanges of items *or* services: the Physician Payments Exception where the *physician* was obtaining and paying for items or services from the DHS Entity, and the FMV Exception where the *DHS Entity* was obtaining and paying for items or services from the physician. Critically, however, whereas the Physician Payments Exception had only one condition—the payment from the physician for the items or services had to be consistent with fair market value—the proposed FMV Exception, like the Personal Services Exception, had myriad requirements. Specifically, HCFA proposed 12 conditions:

1. the arrangement must be "set out in writing,"
2. the agreement must be "signed by the parties,"
3. the agreement must cover "only identifiable items or services," all of which must be "specified in the agreement,"
4. the agreement must cover "all of the items and services to be provided" by the physician to the DHS Entity,
5. the agreement must specify the "timeframe for the arrangement,"
6. the agreement must specify the "compensation that will be provided under the arrangement,"
7. the "compensation, or the method for determining the compensation, must be set in advance,"
8. the compensation must be "consistent with fair market value,"
9. the compensation must "not be determined in a manner that takes into account the volume or value of any referrals,"
10. the arrangement must be "commercially reasonable,"
11. the arrangement must further the "legitimate business purposes of the parties," and
12. the arrangement must meet a safe harbor under the federal Anti-Kickback Statute.[42]

In addition to proposing the FMV Exception (and several other exceptions), HFCA proposed a change to the Physician Payments Exception as part of the 1998 rulemaking.[43] Although seemingly benign at the time, this change would end up serving as the beginning of the end of the Physician Payments Exception. The agency's desire to change the Physician Payments Exception appears to have been motivated by the following concern:

- As noted above, the Space & Equipment Rental Exception is a "two-way" exception; that is, it covers arrangements pursuant to which either the DHS Entity or the physician is paying the other to rent space or equipment.
- Like the Personal Services and (proposed) FMV Exceptions, the Space & Equipment Rental Exception has a host of conditions and requirements. In the case of a space lease, for example (1) the lease has to be "set out in writing," (2) the lease has to be "signed by the parties," (3) the lease has to "specif[y] the premises covered by the lease," (4) the lease has to have a term of at least one year, (5) the rental charges over the term of the lease have to be "set in advance," (6) the rental charges have to be "consistent with fair market value," (7) the rental charges cannot be "determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties," and so on.[44]
- Where a physician leases space or equipment from a DHS Entity, could the parties avoid these various requirements simply by relying on the Physician Payments Exception, which requires only that the physician pay fair market value for the "items or services" at issue?

The differences between the Physician Payments Exception, which protects payments by a physician to a DHS Entity, and the Personal Services Exception, which protects payments by a DHS Entity to a physician, are striking.

As a threshold matter, it is not at all clear that a lease is either an "item" or a "service." If not, the agency proposed a solution in search of a problem. In all events, the agency could have simply used the preamble in the 1998 rulemaking to interpret the terms "item" or "service" in the Physician Payments Exception to exclude space or equipment rentals. Indeed, HCFA stated in the preamble that "we do not believe that Congress meant for the 'items or services' exception to cover a rental agreement as a service that a physician might purchase, when it has already included in the statute a specific rental exception, with specific standards" in the Space & Equipment Rental Exception.[45]

The agency did not stop there, however. Nor did it simply address the narrow issue—i.e., preventing parties from using the Physician Payments Exception to avoid the Space & Equipment Rental Exception—by proposing a narrow regulatory fix. Instead, HCFA proposed amending the Physician Payments Exception to protect compensation for items or services only if (1) the price for the items or services was consistent with fair market value, and (2) the arrangement was not "specifically excepted under another" Stark Law exception.[46]

On the one hand, the 1998 proposal was both tortured and overbroad, ignoring the plain structure and language of the statutory exception, which (again) provides that a physician (1) may pay a *laboratory* for *clinical laboratory services* and (2) may pay *any entity* for any "*other* items or services" (i.e., any non-clinical laboratory services) provided payment is consistent with fair market value. On the other hand, and as a practical matter, the 1998 proposal was not particularly troubling because, at the time, there were no exceptions other than the Physician Payments Exception that covered a transaction pursuant to which a physician purchased items or services from a DHS Entity. For example, if a physician wanted to enter into an arrangement pursuant to which a hospital would provide her practice with transcription services, the Physician Payments Exception would still be available because, as of 1998, there was no other available exception. Both the Personal Services and (proposed) FMV Exceptions only protected arrangements under which the DHS Entity was paying the physician for items or services, and not vice versa.

Modifying the FMV Exception from a "one-way" to a "two-way" exception was, of course, significant.

HCFA, and then later CMS, finalized its 1998 proposed rulemaking in three phases: 2001 (Phase I),[47] 2004 (Phase II),[48] and 2007 (Phase III).[49] In 2001, HCFA finalized its proposed FMV Exception, making only a few small changes to its myriad conditions.[50] Significantly, the exception remained "one-way"—that is, it only protected arrangements pursuant to which a DHS Entity paid a physician for items or services, and not vice versa.[51] Thus, in 2001 (as in 1998), CMS' proposed "mutual exclusivity" provision in the Physician Payments Exception remained largely of academic interest: if a physician and DHS Entity wanted to enter into an arrangement pursuant to which the physician would pay the DHS Entity for items or services, the Physician Payments Exception was still the only available exception.

In the 2004 Phase II rulemaking, CMS finalized its proposed change to the Physician Payments Exception. CMS began by noting that in the 1998 proposed rule, it had "proposed to interpret 'other items or services' to mean any kind of items or services that a physician might purchase," excluding "any items or services specifically listed under other compensation exceptions."[52] In other words, the agency explained, "under the proposed rule, exceptions would be mutually exclusive."[53] As in 1998 and 2001, however, this mutual exclusivity remained largely of academic interest. Once again, as of 2004, the Personal Services and FMV Exceptions remained "one-way" and, as such, if a physician and DHS Entity wanted to enter into an arrangement pursuant to which the physician would pay the DHS Entity for services, the Physician Payments Exception remained the only available exception.

The Rabbit Climbs Into the Hat

In the 2007 Phase III Stark Law rulemaking, CMS did not make any changes to the Physician Payments Exception. The agency did amend the FMV Exception, however, "to permit"—for the first time—"application of that [E]xception to arrangements involving fair market value compensation" from a physician to DHS entities.[54] Modifying the FMV Exception from a "one-way" to a "two-way" exception was, of course, significant. Before the amendment, where a physician and DHS Entity wished to enter into an arrangement pursuant to which the physician would pay the DHS Entity for items or services, the arrangement could be protected—under the Physician Payments Exception—as long as the amount paid by the physician to the DHS entity was consistent with fair market value. After CMS amended the FMV Exception—because of the mutual exclusivity clause that CMS superimposed on the Physician Payments Exception in 2004—the parties could only protect the same arrangement under the FMV Exception, meaning that the arrangement would have to meet that Exception's dozen or so conditions and requirements.

In response to criticism about this result, CMS offered three general, generic, and overlapping explanations. First, the neutering of the Physician Payments Exception was "consistent with the overall statutory scheme and purpose" of the Stark Law.[55] Second, it was "necessary to prevent the exception from negating the statute."[56] And third, "the required application of the fair market value compensation exception, which contains conditions not found in the less transparent exception for payments by a physician to a hospital, further reduces the risk of program abuse."[57] None of these arguments is convincing.

Congress enacted the Stark Law. In doing so it created eight statutory exceptions for compensation arrangements. For arrangements involving a DHS Entity paying a physician for services (DHS Entity → Physician), Congress created the Personal Services Exception with its dozen or so requirements. For arrangements involving a physician paying a DHS Entity for items or services (Physician → DHS Entity), Congress created the Physician Payments Exception, which has a single condition—i.e., that the payment is consistent with fair market value.[58] Without a doubt, the contrast between the two exceptions and their respective requirements is striking. That said, there is absolutely no evidence to suggest that the discrepancy reflects anything other than Congress' "statutory scheme and purpose."[59]

Nor, of course, does the application of the Physician Payments Exception *to precisely the arrangements that, by its plain terms, it was intended to protect* somehow "negate" the statute. To the contrary, Congress contemplated and expressly authorized the creation of additional, regulatory exceptions to protect additional compensation arrangements. For example, CMS was perfectly within its right to create the regulatory FMV Exception, which was originally designed to protect something Congress' statutory Personal Services Exception did not: arrangements pursuant to which a DHS Entity purchased "items" (as opposed to "services") from a physician.[60] CMS also was free to later make the FMV Exception apply to both DHS Entities obtaining services from physicians and physicians obtaining services from DHS Entities.[61] What CMS was not permitted to do, however, was to edit the text of the statutory Physician Payments Exception—by adding the mutual exclusivity clause—in such a manner that effectively precludes physicians and DHS Entities from using that exception. That, by definition, serves to negate the Physician Payments Exception.

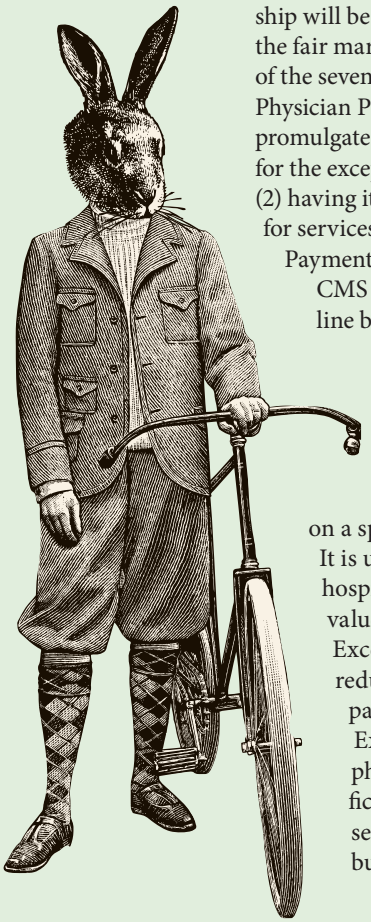
Finally, it certainly is true that the FMV Exception "contains conditions not found in the less transparent" Physician Payments Exception.[62] Moreover, it may very well be that Congress, as a matter of public policy, should have included the same requirements in the Physician Payments Exception that it included in the Personal Services Exception, on the ground that this would have "further reduce[d] the risk of program abuse."[63] But none of that is relevant. Again, the Physician Payments Exception is not the least bit ambiguous: it protects any "payment" by a physician to a DHS Entity for "services" as long as they are "furnished at a price that is consistent with fair market value."[64] It does not require that the arrangement

be in a writing, or be signed by the parties, or have a specific term, or include any of the other myriad conditions included by Congress in the Personal Services Exception or by CMS in the FMV Exception.

Simply put, then, when CMS made the FMV Exception a "two-way" exception in 2007—without, at the same time, eliminating the mutual exclusivity provision that it incorporated into the Physician Payments Exception in 2004—the agency effectively eliminated the *statutory* Physician Payments Exception by making it unavailable for services arrangements. But CMS, of course, cannot amend statutes. It can interpret them (subject to certain limitations) but it cannot rewrite them (or portions of them) out of existence.

In a recent D.C. Circuit case involving another example of CMS overreach relating to the Stark Law—*Council For Urological Interests v. Burwell*, 790 F.3d 212 (D.C. Cir. 2015)—the court noted that "[w]hen Congress gives an agency authority to interpret a statute, we review the agency's interpretation under the deferential two-step test" set forth in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.,* 467 U.S. 837 (1984).

> At step one, to determine whether Congress has directly spoken to the precise question at issue, we use "the traditional tools of statutory interpretation." *Consumer Elecs. Ass'n v. FCC*, 347 F.3d 291, 297 (D.C. Cir. 2003) (internal quotation marks omitted). If it is clear that Congress has addressed the issue, we give effect to congressional intent. If the statute is silent or ambiguous on the matter, we move to a second step that asks whether the agency's interpretation is "based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. An interpretation is permissible if it is a "reasonable explanation of how an agency's interpretation serves the statute's objectives." *Northpoint Tech., Ltd. v. FCC*, 412 F.3d 145, 151 (D.C. Cir. 2005). If the agency's construction is reasonable, we defer. *See Chevron*, 467 U.S. at 842-43.[65]



CMS' rulemakings relating to the Physician Payments Exception does not survive step one of the *Chevron* analysis, much less step two. Using the "traditional tools of statutory interpretation"—starting, of course, with the plain language of the statute in question—Congress clearly and directly addressed the question of whether payments by a physician to a DHS Entity for services could qualify for an exception to the Stark Law's prohibitions; they can, under the Physician Payments Exception, as long as they are "furnished at a price that is consistent with fair market value."[66]

In sum, of the eight compensation arrangement exceptions that Congress created between 1989 and 1993, only one—the Physician Payments Exception—protects arrangements whereby a physician pays a DHS Entity for services.

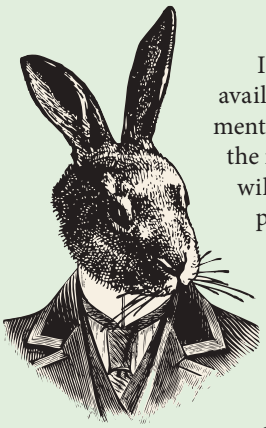
As Judge Henderson concluded in *Council for Urological Interests*, "[a]n agency cannot use its delegated authority in a way that contradicts the Congress's unambiguous intent."[67]

> As a matter of first principles, an agency is not entitled to *Chevron* deference unless the Congress "has left a gap for the agency to fill." If the Congress has "directly spoken" to the issue in question, there is no such gap. An agency crosses an impermissible line when it moves from interpreting a statute to rewriting it.[68]

Congress left no "gap" to "fill" in the case of the Physician Payments Exception. It spoke clearly and directly: where a physician pays a DHS entity for services, that financial relationship will be protected as long as the payment is consistent with the fair market value of the services. Moreover, in contrast to six of the seven other statutory exceptions to the Stark Law,[69] the Physician Payments Exception does not provide that CMS may promulgate additional conditions that must be satisfied in order for the exception to be met. By (1) creating the FMV Exception, (2) having it cover payments by a physician to a DHS Entity for services, and (3) then forbidding the use of the Physician Payments Exception to protect the exact same arrangement, CMS did not simply cross, it leapt, over the impermissible line between interpreting a statute and rewriting it.

Postscript

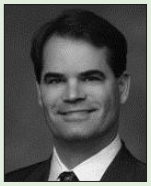
Is this much ado about nothing? If only. Assume a physician and hospital enter into an arrangement pursuant to which the hospital provides certain administrative services to the physician on a sporadic basis between January 1 and December 31. It is undisputed that the payments by the physician to the hospital for the services are consistent with fair market value (the only requirement of the Physician Payments Exception). It also is undisputed that the parties did not reduce their arrangement to a writing signed by both parties (two of the many requirements of the FMV Exception). During the one year period at issue, the physician refers 50 Medicare fee-for-service beneficiaries to the hospital for inpatient and outpatient services. The hospital collects $1,000,000 in reimbursement from Medicare for these services.



If the Physician Payments Exception is available to protect the services arrangement between the hospital and physician, the referrals by the physician to the hospital will not violate the Stark Law's referral prohibition, the claims submitted by the hospital will not violate the Stark Law's billing prohibition and, as such, neither party will have any liability under the Stark Law. If the Physician Payments Exception is not available to protect the services arrangement between the hospital and physician—on the ground that CMS is permitted to prevent the parties from using that (statutory) exception on the ground that the (regulatory) FMV Exception also is available to protect such arrangements—then the hospital could owe the federal government millions of dollars. Why? Where a hospital submits a claim for reimbursement to Medicare for hospital services that were furnished pursuant to a referral that violated the Stark Law, that claim is considered "false" for purposes of the FCA.[70] Under the FCA, the submission of a false claim can result in the payment of treble damages and a fine of up to $21,916 per claim.[71] Here, then, the hospital's exposure would exceed $4,000,000 ($3,000,000 in damages and $1,095,800 in penalties).

To summarize: if CMS is not allowed to write the Physician Payments Exception out of the Stark Law, the hospital has $0 in potential exposure; and if CMS is allowed to write the Physician Payments Exception out of the Stark Law, the hospital has over $4,000,000 in potential exposure.

So, yes, the rabbit needs to be taken out of the hat, and set free. C



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Endnotes

1 42 U.S.C. § 1395nn (2016).
2 42 C.F.R. §§ 411.350-411.357 (2016).
3 31 U.S.C. § 3729 et seq. (2016).
4 42 U.S.C. § 1395nn(a)(1)(A) (2016).
5 DHS are defined both by statute and regulations. In addition to hospital inpatient and outpatient services and clinical laboratory services, DHS include the following services: physical therapy, occupational therapy, and outpatient speech-language pathology services; radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; and outpatient prescription drugs. 42 U.S.C. § 1395nn(h)(6) (2016); 42 C.F.R. § 411.351 (2016).
6 42 U.S.C. § 1395nn(a)(1)(B).
7 42 U.S.C. § 1395nn(a)(2).
8 42 U.S.C. § 1395nn(h)(1)(B).
9 Omnibus Budget Reconciliation Act of 1990 (Pub. Law 101-508), § 4207(e) (Nov. 5, 1990); Omnibus Budget Reconciliation Act of 1993 (Pub. Law 103-66), § 13562 (Aug. 10, 1993); Social Security Act Amendments of 1994 (Pub. Law 103-432), § 152 (Oct. 31, 1994).
10 *See* Dep't of Health & Human Servs. Office of Inspector Gen., *Financial Arrangements Between Physicians and Health Care Businesses* (OAI-12-88-01410) (May 1989).
11 42 U.S.C. § 1395nn(e)(2) (2016).
12 42 U.S.C. § 1395nn(e)(3).
13 42 U.S.C. § 1395nn(e)(8).
14 *Id.*
15 42 U.S.C. § 1395nn(e)(3)(A)(i)-(iv).
16 42 U.S.C. § 1395nn(e)(3)(A)(v). The Personal Service Exception has other requirements in addition to those set forth above. See id. § 1395nn(e)(3)(A)(vi)-(vii).
17 42 U.S.C. § 1395nn(b).
18 42 U.S.C. § 1395nn(b)(3) (2016).
19 42 U.S.C. § 1395nn(c).
20 *Id.*
21 42 U.S.C. § 1395nn(e).
22 42 U.S.C. § 1395nn(e)(1).
23 42 U.S.C. § 1395nn(e)(6) (2016).
24 42 U.S.C. § 1395nn(e)(5).
25 42 U.S.C. § 1395nn(e)(7).
26 *Id.*
27 42 U.S.C. § 1395nn(e)(4).
28 *Id.*
29 42 U.S.C. § 1395nn(b)(4).
30 42 U.S.C. § 1395nn(e)(1)(A)(vi), (B)(vi) (Space & Equipment Rental Exception); (e)(2)(D) (Employment Exception); (e)(3)(A)(vii) (Personal Services Exception); (e)(5)(C) (Physician Recruitment Exception); (e)(6)(B) (Isolated Transactions Exception); and (e)(7)(A)(vii) (Hospital Group Practice Exception).
31 42 C.F.R. § 411.357(a), (b) (Space & Equipment Rental Exception); (c) (Employment Exception); (d) (Personal Services Exception);(e) (Physician Recruitment Exception); (f) (Isolated Transactions Exception); (h) (Hospital Group Practice Exception).
32 Physician Financial Relationships With, and referrals to, Health Care Entities that Furnish Clinical laboratory Services and Financial Relationship Reporting Requirements Final Rule with Comment Period (Stark I and Reporting Requirements Final Rule), 60 Fed. Reg. 41914, 41982 (Aug. 14, 1995).

33 *Compare* Social Security Act § 1877(e)(8), 42 U.S.C. § 1395nn(e)(8) (2016) ("Payments made by a physician . . . (b) to an entity as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value."), *with* 42 C.F.R. § 357(l), ("Payments made by a physician . . . (b) To an entity as compensation for other items or services that are furnished at a price that is consistent with fair market value.").
34 Stark I and Reporting Requirements Final Rule, 60 Fed. Reg. at 41929.
35 *Id.* at 41944.
36 *Id.*
37 *Id.* at 41950.
38 *Id.* at 41972.
39 *See* Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships Proposed Rule (Stark II Proposed Rule), 63 Fed. Reg. 1659, 1699, 1701 (Jan. 9, 1998).
40 *Id.* at 1725-26, codified as amended at 42 C.F.R. § 411.357(l).
41 Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships Final Rule with Comment Period (Stark II, Phase I Final Rule), 66 Fed. Reg. 856, 919 (Jan. 4, 2001).
42 Stark II Proposed Rule, 63 Fed. Reg. at 1725-26.
43 *Id.* at 1703, 1725.
44 42 U.S.C. § 1395nn(e)(1)(A)(vi), (B)(vi) (2016); 42 C.F.R. § 411.357(a), (b); *see also* Stark II Proposed Rule, 63 Fed. Reg. at 1724.
45 Stark II Proposed Rule, 63 Fed. Reg. at 1703.
46 *Id.* at 1725.
47 Stark II, Phase I Final Rule, 66 Fed. Reg. at 856-965.
48 Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II) Interim Final Rule with Comment Period (Stark II, Phase II Final Rule), 69 Fed. Reg. 16054, 16054-146 (Mar. 26, 2004).
49 Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III) Final Rule (Stark II, Phase III Final Rule), 72 Fed. Reg. 51012, 51012-099 (Sept. 5, 2007).
50 Stark II, Phase I Final Rule, 66 Fed. Reg. at 961-962.
51 *Id.* at 919.
52 Stark II, Phase II Final Rule, 69 Fed. Reg. at 16099.
53 *Id.*
54 Stark II, Phase III Final Rule, 72 Fed. Reg. at 51059, 51094.
55 *Id.* at 51057.
56 *Id.*
57 *Id.*
58 42 U.S.C. § 1395nn(e)(8).
59 See Stark II, Phase III Final Rule, 72 Fed. Reg. at 51057.
60 Stark II Proposed Rule, 63 Fed. Reg. at 1725-26.
61 Stark II, Phase III Final Rule, 72 Fed. Reg. at 51059, 51094.
62 *Id.* at 51057.
63 *Id.*
64 42 U.S.C. § 1395nn(e)(8) (2016).
65 *Council for Urological Interests v. Burwell,* 790 F.3d 212, 219 (D.C. Cir. 2015).
66 42 U.S.C. § 1395nn(e)(8).
67 Council for Urological Interests,790 F.3d at 228 (Henderson, K., dissenting from the court's reasoning in part, but concurring in the court's ruling).
68 *Id.* (citations omitted).
69 The six exceptions are set forth in footnote 31 above.
70 42 U.S.C. § 1395nn(a)(1)(B) (2016); 42 C.F.R § 411.353(b) (2016); 31 U.S.C. § 3729(a) (2016). "The Stark Law expresses Congress's judgment that all services provided in violation of that law are medically unnecessary. By reimbursing Tuomey for services that it was legally prohibited from paying, the government has suffered injury equivalent to the full amount of the payments. In this case, the damage from the false statement came from the payment to an entity that was not entitled to any payment at all." United States ex rel. Drakeford v. Tuomey, 795 F.3d 364, 386-87 (4th Cir. 2015) (internal citations omitted).
71 31 U.S.C. § 3729(a); 28 C.F.R. § 85.5 (2016). For all violations occurring on or before November 2, 2015, FCA civil penalties range from $5,500 to $11,000. 28 C.F.R. § 85.3(a)(9).