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Court Sides With CMS Stark Regulations on Physician-Owned Under Arrangement Service Providers

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On May 24, the U.S. District Court for the District of Columbia in *Council for Urological Interests v. Sebelius*[1] (''CUI'') sided with the Centers for Medicare & Medicaid Services in a lawsuit brought by a group of urologists and upheld CMS's 2008 regulations that prohibited physician-owned ''under arrangement'' service providers under the Stark Law (the ''2008 Rule'').

The court also upheld a parallel part of CMS's regulations that prohibited per-service (or ''per-click'') leases with referring physicians.

The issue in CUI involves a technical part of the Stark Law interpreting what it means to be a provider ''furnishing'' ''designated health services'' (''DHS'').

As is well known, the law prohibits physicians from referring Medicare patients to entities furnishing DHS with which they have a financial relationship unless an exception applies. A financial relationship may be either an ownership or investment interest or a compensation arrangement. Inpatient and outpatient hospital services are classified as DHS.

[1] Slip Op., 09-cv-0546 (BJR).

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The group of urologists was challenging a 2008 regulatory change that characterized their arrangements with hospitals as impermissible ownership arrangements, whereas under CMS's Phase I 2001 interpretation, such arrangements only needed to qualify under the compensation exceptions.

Brief History of Physician-Owned Service Providers

Well before the enactment of the Stark Law, physicians held many types of ownership interests in service providers. In some cases, the services were clearly DHS, for example imaging services, and in other cases they were not, for example lithotripsy, cardiac catheterization, ambulatory surgery and dialysis centers. In some of these cases, the non-DHS service was provided by the physician-owned service provider in the hospital for reimbursement and other reasons.

These historic arrangements followed various models, but in most cases the outside service provider leased space from the hospital, provided equipment and supplies, and employed or contracted for the staff and physicians needed to provide the service.

These services provided by outside physician-owned service providers needed to comply with Medicare's ''under arrangement'' rules.[2] Under these rules the hospital must exercise professional responsibility over the service. In addition, ''The provider must accept the pa-

[2] Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5 – Definitions; § 10.3 - Under Arrangements; CMS Pub. 100-01. http://www.cms.gov/Regulations-and-Guidance/Guidance/. . ./ge101c05.pdf

tient for treatment in accordance with its admission policies, and maintain a complete and timely clinical record on the patient, . . .''[3]

Medicare has historically always treated a service provided by an outside vendor under these rules in the same manner as if it were directly furnished by the hospital itself, as seen for example in the coverage rules for outpatient hospital services.[4]

Many of these physician-owned arrangements were viewed as non-abusive because they involved personal clinical care by the physician owners similar to physician-owned ambulatory surgical centers or dialysis centers.

Because of compliance requirements that these services be provided at fair market value, most of the arrangements with hospitals were structured to assure that the hospitals saved money by buying the service from the physician-owned entity as opposed to providing the service in-house.

Ironically, many of these arrangements contained similar quality and cost-control incentives to the physician-owners as are now advocated by CMS in health care reform demonstration projects.

Legal Background

1. Stark Law Phase 1 Rulemaking

In the development of the Stark regulations that were first promulgated as Phase I in 2001, CMS addressed the question of whether to permit physician-owned under arrangement service providers.

One of the questions CMS addressed was to treat the provider that was ''furnishing'' the DHS as the hospital, and not the physician-owned entity. Under this analysis the physicians did not own the hospital, and so the arrangement between the hospital and service provider needed only to comply with a compensation exception.

Part of the consideration for CMS was that with many of these physician-owned services, the physicians provided personal services as an extension of practice without any evidence of abuse. Examples included physician-owned dialysis, ambulatory surgery, and cardiac catheterization.

As a result, in Phase I, CMS defined the term ''entity'' that was furnishing DHS as ''the entity to which CMS makes payment for the DHS,''[5] meaning the hospital. CMS also made clear that ownership or investment interests do not include a contract between a hospital and a physician-owned under arrangement service provider.[6]

In Phase I CMS also permitted physicians to be paid for leased space and equipment and services under a unit-of-service (also known as a ''per-service'' or ''per-click) methodology.[7] CMS allowed such arrangements based on legislative history suggesting such arrangements were permissible.[8]

2. Subsequent Developments

The Phase I rule allowed the historic relationships, for example by physician-owned lithotripsy and cardiac catheterization providers, to continue. Overwhelmingly, these arrangements were not inherently DHS, but only became classified as DHS because they were provided as hospital services and billed by the hospitals. As hospital services, they became DHS, and subject to the Stark Law. But under the Phase I rule, these arrangements needed only to comply with the applicable compensation exceptions.

As happens so often with regulatory developments, an unintended consequence took place. The Phase I rule did not differentiate between services that are not generally DHS, but become classified in that manner when provided under arrangement, and those services that had always been DHS, such as imaging services.

The Phase I rule also did not differentiate between services personally performed by physicians as an extension of practice and services where the physician's only connection with the referred service was the referral itself. This approach meant that referring physicians were permitted to own, and refer to, imaging joint ventures that provided services under arrangement to hospitals and escape Stark Law scrutiny as long as the arrangement complied with a compensation exception.

To many observers this seemed like an end-run around the fundamental purposes of the Stark Law, especially in situations where the referring physicians played no clinical role in the service.

3. Change In Definition of ''Entity'' Furnishing DHS and New Per-Service Restrictions

In August 2008 as part of the fiscal year 2009 inpatient prospective payment rule, CMS responded to anecdotal complaints and largely ended the ability of physician-owned under arrangement service providers to survive under the Stark Law.[9]

CMS accomplished this change by reversing its Phase I interpretation and historic interpretation of what it means to ''furnish'' a service payable under Medicare. Specifically, CMS amended the definition of ''entity'' to include an entity that has ''performed services that are billed as DHS.''[10]

Importantly, the revised rule only restricted these service providers' ability to furnish the full array of services — space, equipment and supplies, and personnel — needed to perform the service in question.

Because the Stark Law exceptions on their face permit physicians to have physician-owned equipment leasing companies without such companies being characterized as furnishing DHS, CMS made clear the limits on its rulemaking authority: ''We do not consider an entity that leases or sells space or equipment used for the performance of the service, or furnishes supplies that are not separately billable but used in the performance of the medical service, or that provides management, billing services, or personnel to the entity performing the service, to perform DHS.''[11]

Notwithstanding the obvious confusion over the question of what bundle of services would trigger the new ban, CMS declined to provide a specific definition

[3] *Id*.
[4] 42 C.F.R. § 410.27(a)(1)(i).
[5] 42 C.F.R. § 411.351.
[6] 42 C.F.R. § 411.354(b)(3)(iv).
[7] *See, eg*., 42 C.F.R. § 411.357(b)-(c).
[8] 66 Fed. Reg. at 876-78; H.Rep. 103-213 at 814 (1993)
[9] 73 Fed. Reg. 48434 (August 19, 2008). A very small number of such arrangements could qualify under one of the ownership exceptions, for example for rural providers. Social Security Act § 1877(d)(2).
[10] 42 CFR § 411.351 (October 1, 2009).
[11] 73 Fed. Reg. 48726.

  HFRA ISSN 1092-1079

of ''perform'' in the final rule, but stated that the term should have its ''common meaning.''[12]

To further restrict these arrangements, CMS invoked its statutory authority regarding lease of space and equipment arrangements to create ''such other requirements as the Secretary may impose by regulation to protect against program or patient abuse.''[13] Specifically, CMS changed course from the Phase I rule, and banned per-service space and equipment rental arrangements involving referring physicians.[14]

District Court Decision

The case was before the district court on remand from the Court of Appeals for the District of Columbia, which found UCI need not first exhaust its administrative remedies in order to have the case heard on its merits.[15] The court was ruling on cross motions for summary judgment and analyzed the two regulatory changes — definition of the term entity and elimination of per-service leases — under the so-called *Chevron* two-part standard.[16]

1. Standard of Review

As explained by the court, ''The court first must examine the statute to determine whether Congress has spoken directly to the precise question at issue.''[17] ''If the statute is silent or ambiguous with respect to the specific issue, then 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.''[18]

Critical to administrative law jurisprudence, at this stage courts are required to uphold an agency's ''reasonable interpretation'' of the statute in question, giving ''deference'' — known also as *Chevron* deference'' — to the agency's interpretation.[19] ''The agency's interpretation need not be the only possible interpretation, nor even the interpretation deemed *most* reasonable by the courts.''[20]

Of note, only in its analysis of the CMS 2008 change to interpretation of per-service leases did the court identify that the standard of review is somewhat different when courts are reviewing changes in agency interpretation. Here, ''[T]he question raised by the change is whether [CMS] has supported its new reading of [the Stark Law] with a reasoned analysis sufficient to command the court's deference under *Chevron*.''[21]

2. The Court's Analysis of Under Arrangement Services

In the court's *Chevron* step one analysis it focused its attention on the statutory compensation exception permitting group practices to provide services under arrangement.[22]

Plaintiffs understandably had pointed to this exception as the basis for CMS's Phase I statutory interpretation that physician-owned under arrangement service providers did not create an ownership interest, but instead need only be analyzed under the compensation exceptions.

According to CMS in Phase I, ''Congress would not have excepted these relationships from the compensation arrangement restriction, if they were prohibited as an ownership or investment interest.''[23] In contrast, in the 2008 rule, CMS stated, ''[Th]ere 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.''[24]

In response to CUI's argument that this statutory exception would be rendered meaningless by CMS's new definition of furnishing, the court cited approvingly to CMS's response in its brief that ''the exception would still be valuable where the physicians are mere employees (and not owners) of a group practice.''[25]

In other words, these employed, non-equity physicians of group practices would not have an impermissible ownership interest, and could avail themselves of protection under this statutory compensation exception. The court held that the term ''entity furnishing DHS'' was ambiguous and turned to the second step in the *Chevron* analysis.

The court found CMS's new interpretation of ''furnishing'' to be a reasonable interpretation. CUI argued this term was impermissibly vague and that CMS failed to provide meaningful guidance.[26] In contrast, CMS argued that the new definition of furnishing was based on a ''plain language'' definition. In siding with CMS, the court reiterated that its job was only to determine whether CMS's interpretation was reasonable under *Chevron*.

3. The Court's Analysis of Per-Service Arrangements

The court's analysis here followed the same path as with under arrangement services. It found the Stark Law did not expressly permit per-service leases, and that CMS's rulemaking was reasonable.

In the *Chevron* step one analysis, the court was unpersuaded by the clear legislative history that Congress intended to permit such leases. Instead, it concluded, ''Indeed, the Stark Law contains no language — not even ambiguous language — permitting lease payments

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[12] *Id*.
[13] Social Security Act § 1877(e)(1)(A)(vi) and (B)(vi); 73 Fed. Reg. 48713.
[14] 42 CFR § 411.357(a)(5)(ii)(B) and (b)(5)(ii)(B) (October 1, 2009).
[15] *Council for Urological Interests v. Sebelius*, 668 F.3d 704, 712-14 (D.C. Cir. 2011). An earlier case that challenged this same regulation, in which we served as lead counsel, involving several groups of cardiologists who provided under arrangement cardiac catheterization services, was dismissed on procedural grounds in this same district court, but the case was not appealed. *Colorado Heart Institute v. Leavitt* (D.D.C. No. 1:08-cv-01626-RMC).
[16] *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984).
[17] *CUI*, slip op. at 10.
[18] *Id*. (internal citations and quotations omitted)
[19] *Id*.
[20] *Id*. at 10-11 (emphasis in original, internal citations and quotations omitted)
[21] *Id*. at 28-29.
[22] SSA § 1877(e)(7).
[23] 66 Fed. Reg. at 942.
[24] Slip Op. at 16, *citing* 73 Fed. Reg. 48725.
[25] *Id*. at 17.
[26] *Id*. at 19.

calculated according to units of service.''[27] In its Chevron step two analysis the court summarized CMS actions.

In Phase I —

''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. However, in the 2008 Regulations, CMS changed course and prohibited per-click payments in the context of physician self-referrals.''[28]

The court cited approvingly CMS's argument that it was entitled to take prophylactic regulatory action without waiting for ''extensive evidence of program or patient abuse.''[29] The court was sufficiently satisfied with the small number of comments to the 2008 regulations that pointed to abuse with per-service leases to uphold CMS's rulemaking, finding that CMS was not required to ''clear a specific evidentiary hurdle prior to imposing additional restrictions for lease exceptions.''[30]

Comment

Both the 2008 Rule and this court decision clearly could have had different outcomes.

Without question, prior to the enactment of the Stark Law, there were abusive joint ventures, primarily with laboratories, that Congress chose to stop. At the same time, there was a long history of physician-owned services, primarily where the physician-owners provided personal clinical services, which were free of abuse, that Congress chose to permit under the Stark Law. In Phase I, CMS made statutory interpretations that allowed physician-owned under arrangement service providers to continue, along with per-service leases.

Few would argue that CMS had some evidence that some providers were taking advantage of these Phase I decisions to allow these physician-owned services to flourish in ways not intended – particularly with imaging services.

In deciding how to address these problems, CMS had options to take a more surgical approach, for example to continue to permit physician-owned under arrangement services where physician owners performed personal clinical services thereby relying on what has come to be known as the ''extension of practice'' exception.

In addition, it is important to note that in the 2008 Rule CMS only restricted physician-owned entities from providing *all* the components of a service—space, equipment/supplies and personnel. But CMS always has recognized that the Stark Law itself clearly permits physicians to provide one of these three components, and it has never been clear why physicians would not be able to avail themselves of two of these components in one arrangement. So CMS simply shifted the compliance analysis to the question of what combination of services would constitute ''furnishing'' the DHS. CMS has never answered this question.

In turning to the court's analysis, it appears CUI has several arguments to appeal in the hopes of finding a circuit court panel that would be unconvinced by the 2008 Rule and more persuaded by CMS's Phase I analysis.

Most importantly, we can easily imagine another court finding CMS's 2008 definition of ''furnishing'' to be a radical departure from past interpretations, including without limitation its under arrangement rules, and that this new definition is not a common ordinary meaning as CMS purports it to be. In any case, given the ongoing uncertainty in the definition of ''furnishing'' and the likelihood of an appeal, we doubt the issues in this CUI case will go away soon.

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[27] *Id*. at 25.
[28] *Id*. at 27.
[29] *Id*. at 28.
[30] *Id*. at 31, n. 15.

  HFRA ISSN 1092-1079