

THE STARK LAW PAYMENTS BY A PHYSICIAN EXCEPTION: AN UNSUNG HERO

Historically, health care entities looking to avoid potential violations under the Federal Stark Law ("Stark") have not turned to the *Payments by a Physician* exception at 42 C.F.R. § 411.357(i) to protect their operations. A review of the exception's history, however, combined with recent experience with pending submissions to the Centers for Medicare & Medicaid Services ("CMS") under the Self-Referral Disclosure Protocol ("SRDP"), has led to a helpful framework for applying the *Payments by a Physician* exception, such as when evaluating timeshare arrangements with referring physicians.

BACKGROUND

Stark prohibits physicians from referring designated health services to entities with whom the physician or an immediate family member has a financial relationship. Among the many exceptions to this rule, Stark carves out payments made by a physician for fair market value items and services. See 42 U.S.C. § 1395nn(e)(8). In 1995, CMS codified this statutory exception into a regulation at 42 C.F.R. § 411.357(i). CMS has refined the regulation over the years, but since its inception, practitioners believed the *Payments by a Physician* exception was only available for applicable arrangements that were not "specifically **excepted** under another provision in § 411.355 through § 411.357." See 69 Fed. Reg. 16054 at 16140 (Mar. 26, 2004). This eliminated the potential use of the exception if any other Stark exception was applicable.

In CMS's long-anticipated Phase III final regulations to Stark, published on September 5, 2007, CMS rejected (i) a request from a commenter that the exception should be "generally available (rather than available only when another potential exception does not apply)" and (ii) a request to clarify that timeshare arrangements could qualify under the *Payments by a Physician* exception. 72 Fed. Reg. 51012 at 51057 & 50144. Similarly, when CMS approved language for the timeshare exception in section (y) on November 16, 2015, it again rejected requests that the *Payments by a Physician* exception be available when evaluating timeshare arrangements. 80 Fed. Reg. 70886 at 71325-27; see also *id.* at 71327 ("Our position regarding the availability of the exceptions for ... payments by a physician at § 411.357(i) for arrangements involving the rental of office space has not changed.")

On December 2, 2020, in the Final Rule, CMS reconsidered its position and clarified that other regulatory exceptions should not limit the scope of the *Payments by a Physician* exception. 85 Fed. Reg. 77492 at 77603-04. CMS noted that although the *Payments by a Physician* exception "was not meant to apply to compensation arrangements that are specifically excepted by other statutory exceptions," parties could generally "rely on [the *Payments by a Physician* exception] to protect fair market value payments made by a physician to an entity for items or services furnished by the entity, even if a regulatory exception at § 411.357(j) *et seq.* may be applicable." *Id.* at 77604. CMS further noted that a correction notice in 2007 cleared up their intent with respect to the *Payments by a Physician* exception:

In the September 5, 2007 **Federal Register**, the regulation text of the exception for payments by a physician was modified in error. Phase II stated that § 411.357(i) is limited to payments for items or services that are "not specifically *excepted* by another provision in §§ 411.355 through 411.357" (69 FR 16140). The September 5, 2007 **Federal Register** replaced "excepted" with "addressed" (72 FR 51094). The original language of the exception was restored in a correction notice to Phase III and published in the December 4, 2007 **Federal Register** (72 FR 68076).

— 85 Fed. Reg. at 77603, n.12

During recent discussions with CMS, the agency stated it believed practitioners should have known at the time that the *Payments by a Physician* exception was broader than many believed. However, the temporary change from "specifically excepted" to "specifically addressed"—which never actually went into effect—was a typo. Even if it had been an intentional change, it was not clear to health care entities that the use of the word "addressed" changed the meaning. Furthermore, CMS's comments in 2007 and 2015 (noted above) undermined the notion that the *Payments by a Physician* exception should have been interpreted broadly before the 2020 Final Rule revision.

Nevertheless, to further emphasize its position in the Final Rule, CMS stated that while it was maintaining its policy with respect to the statutory exceptions, "we no longer believe that the regulatory exceptions should limit the scope of the exception for payments by a physician." 85 Fed. Reg. at 77604. Consequently, CMS revised the language of the exception to note that it may be used unless the statutory

exceptions, codified at § 411.357(a)–(h), are applicable.

RECENT DEVELOPMENTS

Given the historical commentary surrounding § 411.357(i), health care entities have generally been hesitant to rely on the *Payments by a Physician* exception as a first line of defense. However, as a result of recent experience related to CMS's approach to pending SRDP submissions, the exception may have considerable utility, particularly for timeshares.

Why Use the Payments by a Physician Exception?

In general, the *Payments by a Physician* exception is easier to meet than other exceptions. There are no writing, timeframe, or commercial reasonableness requirements. So long as the payment is made by a physician (or an immediate family member) (1) to a laboratory in exchange for clinical laboratory services or (2) to an entity as compensation for fair market value services for which *statutory* exceptions do not apply, the exception may be met. Consider the following example.

Timeshare Example

Effective January 1, 2016, CMS finalized the Stark exception for timeshare arrangements codified in **42 C.F.R. § 411.357(y)** (the "Timeshare Exception"). The Timeshare Exception was created to distinguish between (1) a license or permission to use property where the possessory interest remains with the licensor (a timeshare) and (2) a lease that transfers dominion and control of the property from the lessor to the lessee (a lease). See **80 Fed. Reg. 71325-33**.

For an arrangement that would be considered a timeshare under current CMS guidance, the first step would be to determine if it meets the Timeshare Exception. If the arrangement does *not* meet all elements (e.g., it is not in writing), the parties may potentially rely on the *Payments by a Physician* exception instead.

Important Caveats

Although the timeshare example shows how the *Payments by a Physician* exception may be used in certain cases, it is important to be aware of arrangements where a *statutory* exception might apply. For instance, the *Payments by a Physician* exception may **not** be used for the rental of office space. Each scenario must be evaluated on its own facts and circumstances. Additionally, the exception does not apply when the physician is the party providing the timeshare services and receiving payments.

Moving Forward

Although historically underused, CMS has confirmed through recent SRDP submissions that the *Payments by a Physician* exception may apply more broadly than previously thought. Each arrangement is unique, and we recommend seeking counsel to determine whether the exception can be relied upon in a given situation. Hall Render remains available to help structure arrangements in a legally compliant manner and advise on retroactive analyses for potential SRDP submissions.

PRACTICAL TAKEAWAYS

- The *Payments by a Physician* exception may be broader than previously understood. Following CMS's 2020 Final Rule and recent SRDP submissions, this exception can potentially apply even when other regulatory exceptions are available.
- Consider this exception when evaluating non-traditional arrangements. For timeshare arrangements or other compensation models that may not meet the full requirements of other Stark exceptions, this pathway may offer a viable compliance option.
- Don't overlook historical arrangements. Entities submitting under the SRDP for conduct predating 2020 may be able to rely on this exception, particularly where CMS has clarified its longstanding interpretation.
- Each arrangement still requires a fact-specific analysis. While the *Payments by a Physician* exception is less burdensome procedurally, its applicability still hinges on whether statutory exceptions are implicated and whether the physician is the paying party.

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