



**SCOPE OF REFUND OBLIGATION
IN LIGHT OF STARK VIOLATION**

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Scope of Refund Obligation In Light of Stark Violation

I. The Scope of the Stark Statutory Refund Obligation is Extremely Narrow

A. The Statutory Refund Requirement

The Stark statute provides only that “[i]f a person collects any amounts that were billed in violation of [42 U.S.C. § 1395nn(a)(1)], the person shall be liable to the individual for, and shall refund on a timely basis to the individual, any amounts so collected” (emphasis added). 42 U.S.C. § 1395nn(g)(2).

B. The Regulatory Refund “Requirement” Far Exceeds the Scope of the Statutory Refund Obligation

CMS has attempted to expand the statutory refund requirement as follows:

“An entity that collects payment for a designated health service that was performed under a prohibited referral must refund all collected amounts on a timely basis, as defined in § 1003.101 of this title.”

(emphasis added). 42 C.F.R. §411.353(d).

C. Is The Regulation Enforceable?

1. Scope of administrative agency authority generally proscribed by statute.
2. Specific language inserted in Stark statute where Congress intended Secretary to expand scope of statute; refund obligation section not so designated.

II. Civil Monetary Penalty Provisions Present the Same Ambiguities

A. The Statutory CMP Provision Regarding Refunds

Any person that presents or causes to be presented a bill or a claim for a service that such person knows or should know is for a service for which payment may not be made under paragraph (1) or for which a refund has not been

made under [42 U.S.C. § 1395nn(g)(2)] shall be subject to a civil money penalty of not more than \$15,000 for each such service.

(emphasis added). 42 U.S.C. § 1395nn(g)(3).

B. The Regulatory CMP Provision Regarding Refunds

The OIG may impose a CMP against any person that:

[h]as not refunded on a timely basis (sixty days from collection)...amounts collected as the result of billing an individual, third party payer or other entity for a designated health service that was provided in accordance with a prohibited referral as described in §411.353 of this title.

(emphasis added). 42 C.F.R. §1003.102(b)(9).

C. The CMP Related to Improper Stark Claims

1. CMPs may be imposed against any person who has “knowingly presented, or caused to be presented, a claim which is for...a payment that the person knows, or should know, may not be made under § 411.453 of this title.” 42 C.F.R. § 1003.102(h)(5)
2. But CMP focuses on claim, not failure to refund
3. CMP also includes scienter element

GRAPHIC COMPARISON OF STATUTORY/REGULATORY REFUND AND RELEVANT CMP LANGUAGE

<u>Provision</u>	<u>Statute</u>	<u>Regulation</u>	<u>Discrepancy?</u>
General Prohibition Against Referrals, Billing and Claims Submission	If a physician (or an immediate family member of such physician) has a financial relationship with an entity..., then (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and (B) the entity may not present or cause to	A physician who has a direct or indirect financial relationship with an entity, or who has an immediate family member who has a direct or indirect financial relationship with the entity, may not make a referral to that entity for the furnishing of DHS for which payment otherwise may be made under Medicare.... An entity that furnishes DHS	No. Both the statute and the regulations make clear when referrals are illegal and that claims or bills for services rendered pursuant to a prohibited referral may not be presented to individuals, third party payors or other entities.

<u>Provision</u>	<u>Statute</u>	<u>Regulation</u>	<u>Discrepancy?</u>
	<p>be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a [prohibited] referral.</p> <p>42 U.S.C. § 1395nn(a)(1)</p>	<p>pursuant to a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral.</p> <p>42 C.F.R. § 411.353(a) & (b)</p>	
Refund Required	<p>If a person collects any amounts that were billed in violation of subsection (a)(1) of this section, the person shall be liable to the individual for, and shall refund on a timely basis to the individual, any amounts so collected.</p> <p>42 U.S.C. § 1395nn(g)(2)</p>	<p>An entity that collects payment for a designated health service that was performed under a prohibited referral must refund all collected amounts on a timely basis, as defined in Sec. 1003.101 of this title.</p> <p>42 C.F.R.0 § 411.353(d)</p>	<p>Yes. After articulating that claims could be illegally made upon individuals, third party payors or other entities, statute requires refunds only of <u>certain</u> claims - those paid by "individuals," while regulation requires refund of "all collected amounts."</p>
Civil Monetary Penalty Applicable to Refunds	<p>Any person that presents or causes to be presented a bill or a claim for a service that such person knows or should know is for a service for which payment may not be made under paragraph (1) or for which a refund has not been made under paragraph (2) shall be subject to a civil money penalty of not more than \$15,000 for each such service.</p> <p>42 U.S.C. § 1395nn(g)(3)</p>	<p>Any person that has not refunded on a timely basis, as defined in Sec. 1003.101 of this part, amounts collected as the result of billing an individual, third party payer or other entity for a designated health service that was provided in accordance with a prohibited referral as described in Sec. 411.353 of this title.</p> <p>42 C.F.R. 1003.102(b)(9)</p>	<p>Yes. Statute imposes CMPs only on failure to refund as required "under statute," i.e., to individuals. Regulation expands authority of agency beyond scope of statute, to impose CMPs on failure to refund not only to individuals, but also third party payers and other entities.</p>

III. Evaluating Other Potential Legal Bases "Requiring" Refund of Improper Stark Payments

A. Medicare / Medicaid / Social Security Act Sources¹

1. What Constitutes an "Overpayment" (42 U.S.C. § 1395gg)

¹ See Nessim outline re: 42 U.S.C. § 1320a-7b(a)(3).

2. FI/Carrier Instructions and Forms Related to “Overpayments”
3. Proposed Rules Requiring Refund of Overpayments

B. Other Sources to Consider in Evaluating Refund Obligation

1. Corporate Integrity Agreement
2. Client Compliance Plan
3. Sarbanes Oxley (publicly traded companies)
4. Common Law Theories of Recovery

IV. Strategic Reasons For Initiating Voluntary Refund/Overpayment Efforts

A. Mitigation of Risks/Damages

1. Minimize whistleblower opportunities
2. Reduce False Claims Act damages
3. More favorable administrative sanctions (CIA versus CCA)
4. Avoid criminal exposure

B. Maintain Control of Events

1. Reduce risk of subpoenas, interviews/depositions of employees, and other formal discovery processes
2. Reduce/eliminate surprise
3. Maintain measure of client serenity

C. Send Correct Signals of Priorities/Values

1. Internally to employees/staff
2. Externally to government/customers/competitors/media.