DEALING WITH THE GOVERNMENT WHEN A STARK VIOLATION IS DISCOVERED

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DEALING WITH THE GOVERNMENT WHEN A STARK VIOLATION IS DISCOVERED: THE DISCLOSURE/REFUND DECISION

I. WHAT IS THE REFUND OBLIGATION WHEN A STARK VIOLATION IS DETECTED?

A. The Stark Refund Obligation is Ambiguous

1. The Statute's 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).

2. 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).

3. Is The Regulation Enforceable?

a. Scope of administrative agency authority generally proscribed by statute.

b. Specific language has been included in Stark statute at other points where Congress intended to permit Secretary to expand scope of statute; refund obligation section is not so designated.

B. The Stark Civil Money Penalty Law Refund Provisions Present Similar Ambiguities

1. The Statutory CMP Provision Regarding Refunds

> ....claims paid improperly 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).

2. The Regulatory CMP Provision Regarding Refunds

The OIG may impose a CMP against any person who:

> [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).

GRAPHIC COMPARISON OF STATUTORY/REGULATORY REFUND AND RELEVANT CMP LANGUAGE

Provision	Statute	Regulation	Discrepancy?
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 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. **42 U.S.C. § 1395nn(a)(1)**	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 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. **42 C.F.R. § 411.353(a) & (b)**	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.
Refund Required	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. **42 U.S.C. § 1395nn(g)(2)**	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. **42 C.F.R.0 § 411.353(d)**	Yes. After articulating that claims could be illegally made upon individuals, third party payors or other entities, statute requires refunds only of certain claims – those paid by "individuals," while regulation requires refund of "all collected amounts."
Stark Civil Money Penalty Applicable to 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 paragraph (2)** shall be subject to a civil money penalty of not more than $15,000 for each such service. **42 U.S.C. § 1395nn(g)(3)**	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. **42 C.F.R. 1003.102(b)(9)**	Yes. Statute imposes CMPs on failure to refund as required "under statute," i.e., to individuals. Regulation expands CMP authority beyond scope of statute, to impose CMPs on failure to refund not only to individuals, but also third party payers and other entities.

C. Other Sources To Consider in Assessing Refund "Obligation"

1. Corporate Integrity Agreement

2. Corporate Compliance Plan

3. Sarbanes Oxley (for publicly traded companies)

II. IS THERE AN OBLIGATION TO "DISCLOSE" THE FACT THAT A STARK VIOLATION HAS OCCURRED?

Hypothetical

During a hospital's routine audit of physician compensation agreements it is discovered that from 2003-2005 a physician group performed EKG services at the hospital without a written agreement, but were paid fair market value for their services. You are advised that the Medicare claims paid the hospital as a result of the referrals from these physicians exceeded $2 million. Do you have a duty to disclose the prior unwritten relationship to the government?

A. The Disclosure Obligation

Whoever –

> Having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized,
> ...
>
> shall
>
> (i) in the case of such a statement, representation, concealment, failure or conversion by any person in connection with the furnishing (by that person) of items or services for which payment is or may be

made under the program, be guilty of a felony, and upon conviction thereof fined not more than $25,000 or imprisoned for not more than 5 years or both, or (ii) in the case of such a statement, representation, concealment, failure or conversion by another person, be guilty of a misdemeanor and upon conviction thereof fined not more than $10,000 or imprisoned for not more than one year, or both. 42 U.S.C. § 1320a-7b(a)(3).

1. The Murky Scope of this Criminal Statute May Render it Unenforceable

a. Who is Covered by the Disclosure Obligation?

... "his initial or continued right to any benefit or payment...of any other individual in whose behalf he has applied....

Query: Does the statute cover only individuals, or does it reach corporations? Does it reach those who accept assignment?

b. How Are the "Mind Set" Elements of the Statute to be Measured??

(1) What "event" is the focus of the "knowledge" requirement (the unwritten agreement)?

(2) When must "knowledge" be shown to exist? At the time of the event? At any time?

(3) What is the scienter standard with regard to the filing of the claim? Actual knowledge? "Knew or should have known"? Knowledge that filing a claim in such circumstances would affect its right to payment?

(4) What is the mind set that would need to be shown to constitute "concealment"?

(5) How is the "intent fraudulently to secure" standard to be applied?

c. Additional Indicia of Vagueness

(1) Does "to secure" mean "to obtain" or "to keep"? If it means "to obtain" and claim has already been received, post-receipt discovery not covered.

(2) What "event" must be disclosed? The payments to the physician? Claims resulting from referrals? How detailed would a disclosure need to be?

(3) To whom would a disclosure be made?

d. Summary of Bases for Questioning Relevance of the Statute to Hypothetical

(1) Vagueness – Statute will not be enforced if it "either forbids or requires the doing of an act in terms so vague as that a man of common intelligence must necessarily guess at its meaning and differ as to its application." U.S. v. Lanier, 520 U.S. 259 (1997).

(2) Violation of Fifth Amendment Rights if applied to individual.

(3) Rule of Lenity--strict construction of criminal statute required.

e. Other Factors Affecting Practical Application of Statute

(1) Prosecutorial Discretion – would DOJ choose to test the application of this criminal statute in a matter involving a "technical" Stark violation?

(2) Reaction of Judiciary – would courts be sympathetic to use of this criminal weapon given nature of the Stark violation and the arsenal of civil and administrative penalties already available?

f. What is the Role of Counsel in Advising Client Re: Disclosure Statute

(1) Difficult to render legal opinion re: non-applicability of statute.

(2) Defending client's non-disclosure based upon statute's infirmities – presents more appealing approach.

III. STRATEGIC REASONS FOR INITIATING VOLUNTARY DISCLOSURE/REFUND 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 potential criminal exposure
5. Avoid successful common law theories of recovery

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. To employees/staff

2. To government (OIG and DOJ)

3. To customers/competitors

IV. RESOLVING PROBLEMATIC STARK LAW CLAIMS AS OVERPAYMENTS

A. Definition of Medicare/Medicaid "Overpayment" (42 U.S.C. § 1395gg) Does Not include Claims Paid in Wake of Stark Violation

B. Overpayment Remedy May Nonetheless Be Appropriate Remedy in Many Circumstances

1. Stark violation does not automatically lead to damages greater than repayment.

2. Refund of claims paid should resolve any Stark violation unless person "knew or should have known" that claim was inappropriate.

3. Where technical violations are involved, "mere mistake" or even "simple negligence" likely to have occurred; not sufficient to meet scienter requirement.

4. Acceptable forum for repayment may be at fiscal intermediary/carrier level, not necessarily at OIG level.

V. OIG OPEN LETTER RE: STARK DISCLOSURES (4/26/06)

A. Traditional OIG Provider Self-Disclosure Protocol ("SDP") Affords An Unappealing Process for Resolving Stark Violations

1. Difficult for OIG to convince providers that use of SDP was worth it; calculus of whether to embark upon Stark Law disclosure strategy is often based instead upon likelihood of whistleblower action or government detection, OIG efforts to encourage disclosures has been frustrated.

2. Finalization of Phase II Stark II rules eliminated "technical violation" rationale for non-disclosure; providers were left with difficult dilemma when technical violations are detected.

3. Requires concession that "false claim" submission likely to have occurred.

4. Financial exposure is significant (CMP damages of 2 x claims or greater).

5. Imposition of CIA in many cases.

B. OIG Open Letter Established New Enforcement Initiative to Encourage Stark Law Disclosures

1. Initiative limited to matters involving a financial benefit "knowingly conferred by a hospital upon one or more physicians."

2. Under new initiative, Stark and anti-kickback-based disclosures to OIG will first be screened by DOJ; proposed OIG resolution will also be reviewed by DOJ; satisfaction of OIG will not be binding on DOJ.

3. Damages continuum upon which such cases can be settled runs from:

   - Stark-based CMP damage calculations based on the number and dollar value of improper claims

- Anti-kickback-based CMP damage calculation based on the number and dollar value of improper payments or remuneration to the physician.

4. Subject to the facts and circumstances of each case, the OIG will "generally settle SDP matters" for an amount "near" the lower end of the continuum: "a multiplier of the value of the financial benefit confirmed by the hospital upon the physician(s)."

5. CCA, or CIA, or no additional compliance measures may also be imposed.

6. Participation in initiative contingent upon full cooperation and complete disclosure.

C. Remaining Issues/Concerns

1. Protocol is available only for "knowing" violations; "innocent" Stark violations may still be in limbo.

2. What does "financial benefit knowingly conferred" really mean? How close is this to an admission of an anti-kickback violation? Fifth Amendment issues? What will DOJ's reaction be to such a concession?

3. Repayment of claims paid would also need to be made in addition to SDP settlement.

4. Unclear whether "financial benefit" is total compensation paid or only the difference between actual compensation and FMV.

5. No clear cut guarantees re: a) level of damage multiple, b) how broad any further review of client's physician relationships would need to be, c) when involvement of DOJ would arise.