

FRAUD AND ABUSE CONCERNS FOR ELECTRONIC PRESCRIBING AND ELECTRONIC HEALTH RECORDS

**Presented by:
Peter M. Hoffman, Esq.
Garfunkel, Wild & Travis, P.C.
(516) 393-2268
phoffman@gwtlaw.com**

THE FEDERAL ANTI-KICKBACK STATUTE

42 U.S.C. § 1320a-7b(b)

Makes it unlawful to knowingly and willfully:

- solicit,
- receive,
- offer, or
- pay

any remuneration in return for or to induce a patient referral or other business payable, in whole or in part, under a Federal health care program (e.g., Medicare and Medicaid).

THE FEDERAL ANTI-KICKBACK STATUTE

- Remuneration: includes virtually anything of value (e.g., cash, cash equivalents, kickbacks, bribes, rebates, etc.) that is given directly or indirectly, overtly or covertly, in cash or in kind.
- The OIG, in particular, has a longstanding concern regarding the provision of free or reduced cost items/services to actual or potential referral sources. This could include, e.g., donations of E-prescribing and EHR technology.
- Both sides of an illegal arrangement are liable.

THE FEDERAL ANTI-KICKBACK STATUTE

Possible consequences include:

- Violation of the Federal Anti-Kickback Statute is a crime punishable by a \$25,000 fine and/or five years in jail,
- Conviction may lead to exclusion from Federally funded health care programs (e.g., Medicare and Medicaid), and
- May also be a violation of the federal Civil Monetary Penalties Law.

THE FEDERAL ANTI-KICKBACK STATUTE

Exceptions/Safe Harbors

- The Anti-Kickback Statute is extremely broad in what it prohibits.
- Thus, Congress provided for certain statutory exceptions and allowed for “safe harbor” regulations that protect certain types of arrangements in which the potential for abusive referral or purchasing practices is deemed to be minimal.

THE FEDERAL ANTI-KICKBACK STATUTE

- If an arrangement meets every requirement of the applicable exceptions or “safe harbors,” it will be protected from prosecution under the law.
- Failure to meet an exception/safe harbor, however, does not render an arrangement *per se* illegal: a case-by-case analysis will apply.

BASIC FEDERAL STARK LAW PROHIBITION

42 U.S.C. § 1395nn

- A physician is prohibited from making referrals to an entity for the furnishing of certain “designated health services” reimbursable by Medicare if the physician (or an immediate family member) has a direct or indirect financial relationship (i.e., ownership, investment interest, or compensation relationship) with that entity.
- Relationships involving E-prescribing and/or EHR technology can raise Stark issues.

STARK IS A STRICT LIABILITY LAW

- No requirement of an “intent” to induce referrals
- Compare to Anti-Kickback Statute
- If the basic prohibition is implicated and no exception is satisfied, Stark is violated.

PENALTIES FOR VIOLATING STARK INCLUDE:

- Denial of payment
- \$15,000 civil monetary penalty for each claim submitted as a result of an improper referral
- Refunding of every payment received for services that were referred in violation of the law
- \$100,000 civil monetary penalty for entering into a “circumvention scheme”
- Possible exclusion from Federal health care programs (e.g., Medicare and Medicaid)
- Possible liability under the Federal False Claims Act

THE GOAL

To balance fraud and abuse concerns against the “important national policy” to promote the widespread adoption of health information technology to improve patient safety, quality of care and efficiency in the delivery of health care services.

I. E-PRESCRIBING

E-PRESCRIBING

- **THE OIG HAS ISSUED A FINAL RULE TO ESTABLISH A NEW “SAFE HARBOR” UNDER THE FEDERAL ANTI-KICKBACK STATUTE (AKS) INVOLVING THE PROVISION OF CERTAIN E-PRESCRIBING ITEMS AND SERVICES (71 Fed. Reg. 45110), AND**
- **CMS HAS ISSUED A FINAL RULE CREATING AN EXCEPTION UNDER THE STARK LAW (71 Fed. Reg. 45140).**

E-PRESCRIBING

- **THE E-PRESCRIBING RULES ISSUED BY THE OIG AND CMS ARE NEARLY IDENTICAL.**
- **BOTH RULES ARE EFFECTIVE OCTOBER 10, 2006.**
- **THE E-PRESCRIBING RULES ARE STATUTORILY MANDATED. AS A RESULT, THEY ARE NARROWLY CONSTRUCTED AND OF QUESTIONABLE VALUE.**

THE E-PRESCRIBING RULES PERMIT:

1. Non-monetary remuneration consisting of items and services in the form of hardware, software or I.T. and training services
2. That are “necessary” and
3. “Used solely” to receive and transmit electronic prescription information,

IF

ALL of the following are met . . .

DONORS AND RECIPIENTS: WHO MAY GIVE/WHO MAY GET

1. The items and services are provided:

- **By a hospital to a physician who is a member of its medical staff (both Stark and AKS);**
- **By a group practice to [“a prescribing health care professional” who is a member of the group practice (AKS)]; [a physician who is a member of the group (Stark)];**
- **By a PDP Sponsor or MA organization to [pharmacists/pharmacies participating in the network and to prescribing health care professionals (AKS)]; [a prescribing physician (Stark)]**

**DONORS AND RECIPIENTS:
WHO MAY GIVE/WHO MAY GET
(continued)**

“Group Practice” – same as Stark definition, even for the AKS.

“Member of the Group Practice” – Stark definition plus (for AKS only) other prescribing health care professionals (physicians or other health care professionals licensed to prescribe drugs in the State in which the drugs are dispensed) who are owners or employees of the group practice.

USE

2. The items/services are provided as part of, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items/services are furnished.

COMPATIBILITY

With Other Systems

3. The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use or compatibility of the items/services with other E-prescribing or electronic health records systems.

COMPATIBILITY (continued)

“Any Patient”

4. For items/services of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the recipient's right or ability to use the items or services for any patient.

NO QUID PRO QUO

- 5. Neither the recipient (nor an affiliate) makes the receipt of the items or services, or the amount or nature of the items or services, a condition of doing business with the donor.**

UNRELATED TO VOLUME/VALUE OF REFERRALS OR OTHER BUSINESS

- 6. Neither the eligibility of a recipient for the items/services, nor the amount or nature of the items/services, may be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.**

WRITTEN AGREEMENT

7. The arrangement must be in a written agreement that:
 - Is signed by the parties;
 - Specifies the items/services provided;
 - Specifies the donor's cost; and
 - Covers all e-prescribing items/services to be provided by the donor. (All separate agreements can incorporate each other by reference or may cross-reference a master-list, maintained and updated centrally, and available upon request to the Secretary [preserving the “historical record”]).

DONOR'S STATE OF MIND

8. The donor cannot:

- Have actual knowledge,
- Act in reckless disregard, or
- Act in deliberate ignorance

of the fact that the recipient possesses or has obtained items or services that are equivalent to those provided by the donor.

KEY CLARIFICATIONS IN THE FINAL RULES

Scope of Technology

- The E-prescribing rules protect technology necessary and used solely to receive and transmit *any* prescription information, whether related to drugs or other items or services normally ordered by prescriptions (e.g., laboratory tests or durable medical equipment orders).

KEY CLARIFICATIONS IN THE FINAL RULES

Amount of Permissible Donations

- **There is no monetary limit on the value of donations of E-prescribing technology.**

KEY CLARIFICATIONS IN THE FINAL RULES

Certification

- **Certification that the recipient does not already possess technology technically or functionally equivalent to that donated (as mentioned in the proposed regulations) will not be required.**
 - **The government cautions, however, that “prudent” donors may want to make “reasonable inquiries” and document the communications.**
 - **The government does not believe items/services are “necessary” if the recipient already has them or their equivalent. This implicates the donor’s state of mind rules and leads to the suggestion to make and document “reasonable inquiries” to potential recipients.**

KEY CLARIFICATIONS IN THE FINAL RULES

Eligibility of Recipients

- **Donors may not select recipients based on:**
 - **the number or value of prescriptions written by the recipient that are dispensed or paid by the donor (or any other criteria based on business generated between the parties), or**
 - **the overall value of prescriptions written by the recipient or on the volume or value of prescriptions written by the recipient that are reimbursable by Medicare (Stark) or any Federal health care program (AKS).**

KEY CLARIFICATIONS IN THE FINAL RULES

Eligibility of Recipients (Cont'd)

- **Donors may select recipients based on the total number of prescriptions written by the recipient.**

KEY CLARIFICATIONS IN THE FINAL RULES

Examples of What Is/Is Not Covered

- Licenses, rights of use, intellectual property, upgrades and educational support services (e.g., helpdesk and maintenance) can potentially fit within the rules.
- Software that bundles general office management, billing, scheduling, EHR or other functions with E-prescribing does not meet the “used solely” requirement and is not protected. Likewise, providing technology for non-medical, personal purposes (e.g., a computer that has value beyond E-prescribing) is not covered. Nor is the provision of office staff.

II. ELECTRONIC HEALTH RECORDS (EHR)

EHR

- **THE OIG HAS ISSUED A FINAL RULE TO ESTABLISH A NEW SAFE HARBOR UNDER THE AKS FOR THE PROVISION OF CERTAIN ELECTRONIC HEALTH RECORDS ITEMS AND SERVICES (71 Fed. Reg. 45110) AND**
- **CMS HAS ALSO ISSUED A FINAL RULE CREATING AN EXCEPTION UNDER THE STARK LAW (71 Fed. Reg. 45140).**

EHR

- **THE ELECTRONIC HEALTH RECORDS RULES ISSUED BY OIG AND CMS ARE NEARLY IDENTICAL.**
- **BOTH RULES ARE EFFECTIVE OCTOBER 10, 2006.**
- **THE EHR RULES ARE FAR BROADER THAN THE E-PRESCRIBING RULES AND, THUS, PRACTICALLY, ARE LIKELY TO BE OF GREATER USE TO THE HEALTH CARE COMMUNITY.**

THE EHR RULES PERMIT:

- Non-monetary remuneration consisting of items and services in the form of software or I.T. and training services
- That are “necessary” and
- “Used predominantly” to create, maintain, transmit or receive electronic health records,

IF

ALL of the following are met:

DONORS AND RECIPIENTS: WHO MAY GIVE/WHO MAY GET

- 1. The items and services are provided:**
 - By an “entity” (as defined in 42 C.F.R. 411.351) that furnishes DHS to a physician (Stark);**
 - By an individual or entity that provides services covered by a Federal health care program and submits claims or requests for payment, either directly or through reassignment, to the Federal health care program, or by a health plan, to an individual or entity engaged in the delivery of health care (AKS).**

INTEROPERABILITY

2. The software is interoperable at the time it is given to the recipient.

- **“Deemed” interoperable if a certifying body recognized by the Secretary has certified the software within no more than 12 months prior to the date it is provided to the recipient.**

COMPATIBILITY

3. The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility or interoperability of the items or services with other E-prescribing or EHR systems.

COST SHARING

- 4. Before receipt of the items or services, the recipient must pay 15% of the donor's costs.**
 - Neither the donor (nor any affiliated/related party) may finance the recipient's payment or loan funds to the recipient to pay for the items or services.**

NO QUID PRO QUO

- 5. Neither the recipient (nor affiliates) may make the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.**

UNRELATED TO VOLUME/VALUE OF REFERRALS/OTHER BUSINESS

6. Neither the eligibility of a recipient, nor the amount or nature of the items/services, may be determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties.
 - “Deeming” provisions are included (i.e., where the determination is “deemed” not to directly take into account the volume/value of referrals or other business).

**UNRELATED TO VOLUME/VALUE
OF REFERRALS/OTHER BUSINESS**
(Cont'd)

The determination will be “deemed” not directly related if any one of the following is met:

- the determination is based on the total number of prescriptions written by the recipient (not the volume or value of prescriptions dispensed or paid by the donor or billed),

**UNRELATED TO VOLUME/VALUE
OF REFERRALS/OTHER BUSINESS**
(Cont'd)

- the determination is based on the size of the recipient's medical practice (e.g., total patients, total RVU's, or total patient encounters),
- the determination is based on the total number of hours the recipient practices medicine,

**UNRELATED TO VOLUME/VALUE
OF REFERRALS/OTHER BUSINESS**
(Cont'd)

- **the determination is based on the recipient's overall use of automated technology in his/her practice (without specific reference to the use of technology in connection with referrals made to the donor),**
- **the determination is based on whether the recipient is a member of the donor's medical staff, if the donor has a formal medical staff,**

**UNRELATED TO VOLUME/VALUE
OF REFERRALS/OTHER BUSINESS**
(Cont'd)

- the determination is based on the level of uncompensated care provided by the recipient, or
- the determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

WRITTEN AGREEMENT

7. The arrangement must be in a written agreement that:
 - Is signed by the parties;
 - Specifies the items/services being provided;
 - Specifies the donor's cost and the amount of the recipient's contribution; and
 - Covers all of the EHR items/services to be provided by the donor. (All separate agreements can incorporate each other by reference or may cross-reference a master-list, maintained and updated centrally, and available upon request to the Secretary [preserving the "historical record"]).

DONOR'S STATE OF MIND

8. The donor cannot:

- **Have actual knowledge,**
- **Act in reckless disregard, or**
- **Act in deliberate ignorance**

of the fact that the recipient possesses or has obtained items or services equivalent to those provided by the donor.

“ANY PATIENTS”

- 9. For items/services of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the recipient’s right or ability to use the items or services for any patient.**

LIMITATIONS

10. The items/services:

- May not include staffing of the recipient's office.
- May not be used primarily to conduct personal business or business unrelated to the recipient's clinical/medical practice or operations.

E-PRESCRIBING CAPABILITY/ PART D STANDARDS

- 11. The EHR software must contain E-prescribing capability (either by an E-prescribing component or interface ability with the recipient's existing E-prescribing system) that complies with the applicable Medicare Part D standards at the time the items/services are provided.**

COMPLIANCE!

12. The arrangement cannot:

- **Violate the AKS, or any Federal or State law/regulation governing billing or claims submission (Stark).**
- **Shift the costs of the items or services from the donor to any Federal health care program (AKS).**

SUNSET PROVISION

13. The transfer of items/services must occur and all conditions of the Safe Harbor or Stark Exception must be satisfied on or before December 31, 2013.

KEY CLARIFICATIONS IN THE FINAL RULES

No pre- and post-operability bifurcation:

- **Only a single EHR rule for each of Stark and AKS.**

Definition of “Electronic Health Record”

- **Both rules define “Electronic Health Record” as a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.**

KEY CLARIFICATIONS IN THE FINAL RULES

Scope of Technology: EHR Functions Must “Predominate”

- **The EHR rules recognize the reality of integrated software packages. The “core functionality” of the technology must be the creation, maintenance, transmission or receipt of individual patients’ electronic health records.**
 - **Software packages that include other functions directly related to the care and treatment of patients (e.g., patient administration, scheduling, billing and clinical support) may be protected as long as the “core functionality” criteria is met (unlike the E-prescribing rule).**

KEY CLARIFICATIONS IN THE FINAL RULES

Scope of Technology (cont'd)

- There must be an E-prescribing element. Query if this limits the rules' breadth.
- Hardware – including modems and routers, and operating software that makes the hardware function – is not included. Nor are storage devices, items or services used primarily by the recipient for personal business or software with “core functionality” other than EHR (e.g., payroll or human resources, or packages focused primarily on management or billing).
- The rules do not protect the provision of staff to recipients.

KEY CLARIFICATIONS IN THE FINAL RULES

Scope of Technology (cont'd)

- **Software, I.T. and training services “necessary and used predominately” may include, for instance:**
 - **Interface and translation software;**
 - **Rights, license and intellectual property related to the EHR software;**
 - **Connectivity services, including broadband and wireless internet services;**
 - **Clinical support and information services related to patient care (but not separate research or marketing support services);**
 - **Maintenance services;**
 - **Secure messaging (e.g., with patients); and**
 - **Training and support services (e.g., help desk).**

KEY CLARIFICATIONS IN THE FINAL RULES

Permissible Donors

- **Clinical laboratories are included.**

Amount of Protected Donations

- **There is no cap on the amount of protected donations in the final rules.**

KEY CLARIFICATIONS IN THE FINAL RULES

Certification

- Certification that the recipient does not already possess technology technically or functionally equivalent to that donated (as mentioned in the proposed regulations) will not be required.
 - The government cautions, however, that “prudent” donors may want to make “reasonable inquiries” and document the communications.
 - The government does not believe items/services are “necessary” if the recipient already has them or their equivalent. This implicates the donor’s state of mind rules and leads to the suggestion to make and document “reasonable inquiries” to potential recipients.

KEY CLARIFICATIONS IN THE FINAL RULES

Cost Sharing Requirement

- **All donated software and HIT and training services are subject to the cost-sharing requirements.**
 - **This includes, for example, any updates, upgrades or modifications not included in the initial purchase price.**
 - **Parties are advised to use a “reasonable and verifiable” method to allocate costs (particularly for internally–developed software or add-on modules/components) and are “strongly encouraged” to maintain contemporaneous and accurate documentation.**

ARE THESE REGULATIONS THE FINAL WORD?

Maybe Not

THE HEALTH INFORMATION TECHNOLOGY PROMOTION ACT

**In July, the House approved the HIT
Promotion Act of 2005. More changes
could be coming . . .**

STAY TUNED