CMS/OIG RELEASES FINAL RULE FOR DONATING HIT

On August 1, 2006, CMS released its final rule establishing two new exceptions under the Federal Physician Self-referral Law for certain arrangements involving the provision of (1) electronic prescribing (e-prescribing) and (2) electronic health record (EHR) technology. The final rule will appear in the August 8, 2006 *Federal Register* publication. The OIG released a similar final rule establishing two new safe harbors under the Federal Anti-Kickback Statute for e-prescribing (§ 1001.952 (x)) and EHR technology (§ 1001.952 (y)). The rule becomes effective 60 days following publication: Oct. 9, 2006.

Interestingly, CMS and OIG have a provision in the final rule relating to EHR protections sunsetting on December 31, 2013. The reasoning behind the sunset is the belief that the technology will become widely used and an accepted part of medical practice, negating the need for protection. The final rule requires all donations of items and services must occur by then.

SUMMARY OF FINAL RULE

- Elimination of the proposed requirement for the Recipient (physician) to "certify" technology both for EHR and e-prescribing donations. . *ACP requested they eliminate this provision.*

- Replaces the criteria that donated items and services must be "used solely" for transmission and receipt of EHRs, and replaces with the condition that EHR functions must "predominate." In addition, the software must have e-prescribing capability. *ACP requested they consider including multi-use devices to avoid costly unbundling practices.*

- CMS broadens the categories of Donors and physician Recipients of EHRs to include any entity that furnishes DHS may make protected donations to <u>any</u> physician.[1] OIG broadens its categories of Donors to include entities that provide patients with health care items or services covered by the Federal health care program and submit claims for those items or services. *ACP requested broad inclusion when considering adding potential qualified Donors and Recipients (i.e., clinical laboratories, nursing homes, community health centers, etc).*

- Clarifies the definition of Permitted Donations to include connectivity and maintenance services, help desk and other similar support. It does not include hardware. *ACP commented that the final rule should include any equipment (especially hardware), item, information, right, license, intellectual property, software, training, education or service necessary for developing, implementing, operating or facilitating the adoption of electronic prescribing or EHRs.*

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[1] The Self-referral law only applies to physicians, whereas the Anti-kickback Statute is more broad, applying entities that provide covered services and submit claims for payment to a Federal health program.

- Eliminates the desire to place a cap or aggregate limit on donated EHR technology and instead, requires a 15% Donor match. There is no cap or donor match requirement for e-prescribing donations. *ACP commented that we are not supportive of placing a cap or aggregate limits on the amount of technology a Donor may provide and suggested they consider a match instead of a cap.*

I. "Necessary" Nonmonetary Remuneration

A. Certification

Proposed Rule: According to the proposed rule, the exceptions/safe harbors would not protect arrangements in which a Donor provides items or services that are "technically or functionally equivalent to items and services the Recipient currently possesses or has obtained." In addition, the proposed rule would require the Recipient to "*certify*" that the items and services to be provided are not technically or functionally equivalent to items or services the Recipient already possesses or has obtained.

ACP Comments: The College believes that the proposed criterion for "technical and functional equivalent" is ambiguous and needs further clarification. In an environment where advances in technology are constant, this would be a very difficult standard in which to comply. More importantly, we are particularly concerned that the requirement to "certify" that the items are not "technically or functionally equivalent to items or services the Recipient already possesses or has obtained" will amount to an unnecessary and costly burden for physician practices and other Recipients. The vast majority of physicians will be unable to make such a determination without hiring an outside expert in the informatics field with the requisite knowledge. ACP strongly recommends CMS/OIG reconsider this requirement, or remove the obligation to "certify" altogether.

Final Rule: The final rule eliminates the requirement for the physician to "certify" that the items and services provided are not "technically or functionally equivalent" to the items or services the physician already possesses. CMS/OIG believes this "might become unnecessarily burdensome." However, if the Donor knows that the physician already possesses the equivalent items or services, or acts in deliberate ignorance or reckless disregard of the fact, the Donor will not be protected.

B. Divesture

Proposed Rule: Prohibits physician from intentionally divesting themselves of functionally or technically equivalent technology that they already possess to shift the costs to Donors.

ACP Comment: We sought further clarification of CMS/OIG's concern about the risk of Recipient's intentionally divesting themselves of functionally or technically equivalent technology that they already possess to shift the costs to Donors. We do not believe there is substantial risk of intentional divesting technology, however, there may be innocent situations that unfairly trigger a violation of the proposed rule. For example, Recipients

may have some form of technology that, because of its inherent complexities, the practice is not using it to its full potential. A Donor that offers the Recipient a more "user friendly" system along with the necessary training and supports – something the Recipient desperately needs in order to recognize the technology's full-use – should not be in violation of the rule, especially if the Donor is aware of the situation. In addition, there may be a situation where a Recipient relocates or is recruited by a Donor to another geographic area. In that case, if the Recipient divests all of its practice assets, including technology, and accepts the Donors technology should that Recipient (or Donor) be in violation of the law? We believe the final rule should clarify this restriction and draft a rule that is more flexible.

Final Rule: The final rule eliminates reference and concerns over physician divesture.

C. Necessary Definition

Proposed Rule: The proposed rule defines "Necessary" by using examples of hardware, software, broadband or wireless Internet connectivity, training, information technology support services and other items and services used in connection with the transmission or receipt of electronic prescribing information.

ACP Comment: We recommend that this definition implicitly include connectivity services, help desk services and operating system software. Inclusion of items such as these will support the optimum use of information technology while not impinging on efforts to combat fraud and abuse.

Final Rule: The final rule clarifies that the exception/safe harbor protects arrangements involving Nonmonetary remuneration in the form of software or information technology and training services necessary and used predominately to create, maintain, transmit, or receive EHRs. CMS/OIG does not include hardware in this definition. Such protections cover "information technology services," including connectivity and maintenance services. CMS/OIG interprets "training services" to include help desk and other similar support.

II. "Used Solely"

Proposed Rule: The proposed rule protection requires that items and services donated must be "used solely" for the transmission or receipt of electronic prescribing information.

ACP Comment: We believe that the narrowly proposed "used solely" criteria will limit the effectiveness of the proposed rule to facilitate the implementation of HIT. For example, many physicians are currently dissuaded by the 'business case' and practice workflow changes necessary to add electronic prescribing or other forms of technology to their practices. In most practice settings, single purpose electronic prescribing technology is of limited value. While the donation of requisite electronic prescribing hardware, software, and training may affect a change in this position, the inclusion of increased functionality in the donated system (e.g., email capacity, Internet capability, etc.) would further facilitate increased participation by Recipients.

Furthermore, the "used solely" requirement may have the unintended effect of pressuring vendors to "strip-down" already integrated software packages, a practice known as "unbundling," resulting in less office efficiency and ultimately increased practice costs arising from the need to purchase additional technology separately. We are, therefore, requesting consideration of protections that cover increased functionalities in the donations.

Final Rule: The final rule does not adopt its proposal for "used solely". Instead, the rule includes a condition making clear that the EHRs purpose must "predominate." Generally, software that relates to patient administration, scheduling functions, billing, clinical support, etc. can be donated. To qualify for protection, the software must be interoperable (i.e., recognized by certifying body no more than 12 months prior) at the time of donation and the software must contain electronic prescribing capability. In addition, the Donor must not take any steps to disable the interoperability or impose barriers to compatibility of donated technology.

Further examples of protected donations that predominate include:

- Interface and translation software;
- Rights, licenses, and intellectual property related to electronic health records 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 (for example, permitting physicians to communicate with patients through electronic messaging); and
- Training and support services (such as access to help desk services).

CMS/OIG interprets the scope of covered electronic health records technology to exclude:

- Hardware (and operating software that makes the hardware function);
- Storage devices;
- Software with core functionality other than electronic health records (for example, human resources or payroll software); and
- Items or services used by a physician primarily to conduct personal business or business unrelated to the physician's practice.

III. Other Donors and Recipients Protected by the Exceptions/Safe Harbors

A. Scope

Proposed Rule: The proposed rule limits the scope of protected Donors to hospitals, group practices, PDP sponsors, and MA organizations. This is consistent the MMA mandating legislation.

ACP Comments: The College strongly supports the expansion of protections to include other categories of Donors and Recipients within health care that can facilitate the implementation of electronic prescribing and EHRs. Specifically, we recommend the inclusion of clinical laboratories, nursing homes, durable medical equipment (DME) providers, community health centers, other long term care facilities, Network Providers or other entities that operate, support or manage Network Providers; physician-hospital organizations or physician organizations; Regional Health Information Organization (RHIOs), or others designed to enhance the overall health of the community.

Final Rule: The CMS final rule expands the list of EHR Donors to include an entity that furnishes DHS to <u>any</u> physician. Due to this change, the CMS final rule for EHRs will protect clinical laboratories. The OIG final rule clarifies its list of Donors to include hospitals, group practices, physicians, nursing and other facilities, pharmacies, laboratories, oncology centers, community health centers, FQHC's, dialysis facilities, and health plans.

B. <u>Members of the Group Practice & Independent Contractors</u>

Proposed Rule: The proposed rule required that hospitals can only donate technology to physicians on its own medical staff. The proposed rule excluded "independent contractors."

ACP Comment: This strict requirement runs the risk of the hospital providing technology to only certain members of a group practice, potentially isolating other "members of the group practice" who do not have privileges to the Donor hospital. In many cases, other providers within the group practice may cover for independent contractors in their absence and it makes sense that all records of patients are readily available to the practice, regardless of the status of the treating provider. In order to promote continuity of care and avoid a situation where only part of a practice is wired, we believe Donors should be allowed to donate technology to all "members of a group practice," including those who do not routinely provide services to the Donor.

Final Rule: The final rule expands the list of Donors of EHRs to include an entity that furnishes DHS to <u>any</u> physician.

IV. <u>Selective Criteria</u>

Proposed Rule: CMS/OIG proposed that neither the eligibility of a Recipient to receive items and services from a protected Donor, nor the amount or nature of the items or services received, may be determined in a manner that takes into account the volume or value of the Recipient's referrals or other business directly generated between the parties. The proposed rule further clarifies that this exception/safe harbor does not preclude selection criteria that are based upon an <u>indirect</u> measure of business generated by the Recipient (e.g., the total number of prescriptions written by a Recipient of electronic prescribing hardware or software).

ACP Comment: The College supports the need to exclude from protection donations that are a condition of doing business with the Donor, or are a direct result of the volume or value of the amount of business generated by the Recipient to the Donor. We are concerned, however, about the further elaboration that permits selection based upon indirect measures of business generated. We believe that most Donors will employ such selection criteria that will potentially disadvantage small physician practices -- which generate relatively limited business – in competing for donations included in the proposed exceptions/safe harbors.

Final Rule: The final rule dismissed our concerns about disadvantaging small and rule practices, permitting Donors to use selective criteria for choosing physician Recipients, provided that neither the eligibility of a physician, nor the amount or nature of the items or services donated, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. Acceptable criteria to meet the definition include such cases:

1. Based on the total number of prescriptions written by the physician (but not the volume or value of prescriptions dispensed by the Donor);

2. The determination is based on the size of the physician's medical practice (for example, total patients, total patient encounters, or total relative value units);

3. The determination is based on the total number of hours that the physician practices medicine;

4. The determination is based on the physician's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the Donor);

5. The determination is based on whether the physician is a member of the Donor's medical staff, if the Donor has a formal medical staff;

6. The determination is based on the level of uncompensated care provided by the physician; or

7. 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.

V. Value of Protected Technology

Proposed Rule: CMS/OIG proposed to limit the aggregate value of qualifying e-prescribing technology that a Donor can provide, and solicited comment on the methodology for limiting the aggregate value of donate technology. The drafters indicated it was considering setting an initial cap.

ACP Comment: ACP is greatly concerned about limitations on the aggregate fair market value of all items and services provided to a Recipient from a single Donor. The College questions the need for caps or aggregate limits to be placed on donated technology to meet the requirements of the exceptions/safe harbors. There is real question as to how such limitations would implemented, calculated, monitored, and adjusted from year-to year. A more basic question, however, is whether the standard to be used for calculating the cost would be the *fair market value* to the Recipient, or what the *actual cost* is to the Donor, keeping in mind large Donors would be able to leverage economies of scale by buying in bulk. In addition, the per-physician implementation cost to a small physician practice will be much higher than for a medium-to-large physician practice. Therefore, setting a per-physician cap or limitation could greatly disadvantage the smaller practice and limit their overall eligibility. We, therefore, do not believe a cap is warranted or necessary at this time.

Final Rule: The final rule offers protection under this exception/safe harbor only if the physician pays 15% (fifteen percent) of the Donor's cost of the EHR technology (cost-sharing exception). For homegrown software, CMS/OIG encourages the use of "reasonable and verifiable method for allocating costs and are strongly encouraged to maintain contemporaneous and accurate documentation." CMS/OIG notes that all donated software, HIT, and training services are subject to cost-sharing requirements. Any future upgrades, updates, or modifications not covered in the initial purchase agreement are subject to separate cost-sharing obligations by the physician.

In addition, CMS/OIG is requiring documentation of the cost to the Donor of the donated technology, and the physician's contribution to the cost. The documentation must be specific as to the items and services donated, the actual cost to the Donor, and the amount and confirmation of the physician's cost-sharing obligation.

For e-prescribing, CMS/OIG will not limit the value of donations or require a 15 % donor match..

VI. Definitions

A. Electronic Health Record

Final Rule: The final rule defines "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.

B. Interoperability

Final Rule: The final rule defines "interoperability" to mean that, at the time of the donation, the software is able to (i) communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings, and (ii) exchange data such that the clinical or operational purpose and meaning of the data are

preserved and unaltered. This interoperability must apply in various settings, meaning that the software must be capable of being interoperable with respect to systems, applications, and networks that are both internal and external to the donor's or recipient's systems, applications, and networks. In other words, software will not be considered interoperable if it is capable of communicating or exchanging data only within a limited health care system or community.