



AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*

December 12, 2005

Daniel R. Levinson
Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG-405-P
Room 5246, Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute, 42 CFR Part 1001 RIN 0991-AB36 (October 11, 2005)

Dear Inspector General Levinson:

The American College of Physicians (ACP), representing over 119,000 doctors of internal medicine and medical students, appreciates the opportunity to submit comments on the proposed rule, “Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute,” published in the *Federal Register* dated October 11, 2005. This proposed rule would establish new safe harbors under the Federal anti-kickback statute for certain arrangements involving the provision of electronic prescribing and electronic health record (EHR) technology. We applaud the OIG for its expediency in issuing a proposed rule and urge the final rule to be promulgated as soon as possible.

We want to take this opportunity to acknowledge the importance of providing protections to entities considering the donation of electronic prescribing and EHR technology to other entities struggling to come up with the financial means to make the investment. We also recognize the complexity involved with writing a rule that balances the need to speed adoption of information technology with the need to protect patients from fraud and abuse. We believe the Office of Inspector General (OIG) has made a good-faith effort to draft a proposed rule that attempts to strike that balance and we congratulate you on this effort. However, we have significant concerns that the proposed rule does not accomplish what it intends and, in some places, may create unintended consequences that restrict the ability to adopt new technology in the future.

SUMMARY OF COMMENTS

- ACP appreciates the efforts OIG has made in the proposed rule and we urge the prompt and efficient release of the final rule.
- Congress and the Administration must take a greater leadership role in offering financial incentives to providers to accept the increased costs (one-time and ongoing) and practice workflow changes (ongoing) required as part of HIT implementation.
- We are particularly concerned the proposed requirement for the Recipient to “certify” technology poses an undue financial burden and should be either clarified or withdrawn.
- ACP requests flexibility in defining the criteria for “used solely” to avoid the unbundling of multi-use devices, resulting in an added expense.
- The OIG should be as inclusive as possible when considering adding potential qualified Donors and Recipients.
- Permitted donations should be broadly interpreted to 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 EHR.
- We are not supportive of placing a cap or aggregate limits on the amount of technology a Donor may provide.

GENERAL COMMENTS

ACP is well aware of the potential benefit of electronic prescribing and EHRs to the health of Medicare beneficiaries -- and ultimately all Americans -- in terms of decreased medical errors, increased clinical quality of care, and reduced costs for all stakeholders. We strongly support overall efforts in Congress and the Administration to speed the adoption of uniform standards for health information technology (HIT). In particular, ACP supports the efforts of the American Health Information Community (AHIC) and its confirmation of the activities of the Certification Commission for Healthcare Information Technology (CCHIT) to develop a process to certify specific HIT products that meet or exceed a specified level of functionality, interoperability and security.

Within the College, we are firmly committed to providing practicing internists with practical tools to help them improve quality and incorporate quality measures into their practices. ACP’s Physicians Information and Education Resource (PIER) provides ACP members -- at no cost to them -- access to “actionable” evidence based guidelines at the point of care for over 300 clinical modules. ACP’s-own Practice Management Center has developed resources to help internists in the decision-making process on electronic health records and is leading an initiative to provide internists with tools and best practices to help them redesign their office processes to improve health care quality.

While we believe the OIG proposed regulations represent a necessary step toward facilitating the implementation of technology, we do not believe it will result in significant widespread HIT adoption. We do not believe the majority of potential Donors protected by the proposed safe harbors have the necessary financial resources to make a major impact regarding implementation

of this technology. Without sufficient financial assistance from the federal government, particularly to those in small physician practices, we will simply be unable to achieve a smooth transition into a fully-integrated HIT society. Therefore, we believe it is essential to fund initiatives that encourage HIT integration into all health care sectors.

To this end, ACP strongly believes that the Congress and the Administration must take a more active leadership role by offering significant financial incentives for practitioners to accept the increased costs and burdensome practice workflow changes that will be required as part of HIT implementation. Such incentives should include grants, loans, and refundable tax credits to account for the expensive start-up costs for implementation. In addition, there must be recognition of the on-going costs for training, maintenance and periodic upgrades inherent in operating a HIT system. These costs can be addressed by providing a modest Medicare add-on payment for physicians who employ HIT as part of overall quality improvement efforts. These same provisions can be found in the bipartisan legislation, H.R. 747, “the National Health Information Incentive Act.” In addition, we believe the Department of Health and Human Services should act to expand the pay-for-performance Medicare Modernization Act (MMA) Section 649 demonstration to encourage greater participation from small physician practices. We believe that offering meaningful financial incentives is the most effective way to improve quality and expand the use of HIT, especially in small practices.

While ACP does not believe the proposed rule will dramatically increase the overall adoption of HIT, there are enough potential Donors with the financial means considering this option and, therefore, several minor refinements and clarifications should be made in order to yield the greatest possible benefit. In order to have any amount of success, however, it is absolutely essential that the Anti-kickback Statute safe harbors and the Self-referral Law exceptions are completely in line with another.

ACP offers the following comments to the proposed rule:

SPECIFIC COMMENTS & RECOMMENDATIONS

“Necessary” Nonmonetary Remuneration (§1001.952(x)(7)(iv))

According to the proposed rule, the safe harbor 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.

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 will 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.

Particular issues the OIG needs to clarify in the final rule regarding the “certify” provision are: What types of information should be included in the certification? What are the penalties for innocently misstating the technical or functional equivalency of the item or services? Who decides if and to what extent the Recipient misstates the certification? And, given the technical expertise required to make this certification, the OIG should also clarify if it is appropriate to seek outside advice and whether those fees could be paid for by the Donor, and applied to the aggregate limit or cap (should one be adopted)?

Given the multiple complexities and uncertainties surrounding the certification requirement and the ambiguity of items that are “technical and functional equivalent,” we strongly believe the undue burden and added expense required runs counter to the intent of the MMA to further promote the implementation of this technology. ACP strongly recommends the OIG reconsider this requirement, or remove the obligation to “certify” altogether.

In addition, ACP seeks further clarification of 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 of 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 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 OIG should clarify this restriction and draft a rule that is more flexible.

Finally, the OIG includes in the proposed rule “Necessary” definition 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. 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.

“Used Solely” (Section 1860D-4(e)(6))

The College seeks clarification of the requirement that items and services donated must be “used solely” for the transmission or receipt of electronic prescribing information. We believe that

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 safe harbors that cover increased functionalities in the donations. This would be consistent with the proposal to create an additional safe harbor to protect the provision by Donors to Recipients of some limited hardware (including necessary operating system software) and connectivity services that are used for more than one function, so long as a substantial use of the item or service is to receive or transmit electronic prescription information.

Finally, while ACP greatly appreciates the OIG elaborating on what qualifies as “used solely” to a broader “substantial use” definition as it applies to limited hardware and connectivity services, we still believe that even this term would benefit from further clarification. In order to avoid percentages or other confusing criteria, we recommend the OIG allow for more flexibility in allowing multi-purpose devices.

Comments on Other Qualifying Technology

The OIG is soliciting comments on whether the safe harbor should protect qualifying electronic prescription technology that is used for the transmission of prescription information regarding items and services that are not drugs (e.g., supplies or laboratory tests). ACP strongly supports the expansion of safe harbors to protect prescription information on items and services that are not drugs. We believe these can include prescriptions for laboratory tests, supplies and durable medical equipment (DME).

Other Donors and Recipients Protected by the Safe Harbor

The College strongly supports the expansion of the safe harbor to include other categories of Donors and Recipients within health care that can facilitate the implementation of electronic prescribing and EHRs. We understand the OIG was simply responding to the drafting of the MMA legislation and we hope broadening the scope of qualified Donors and Recipients will be received favorably.

Specifically, we recommend the inclusion of clinical laboratories and other types of health care providers such as nursing homes, durable medical equipment (DME) providers, community health centers, and other long term care facilities as potential Donors and Recipients of this technology. The College also supports the inclusion of certain other provider organizations, such

as Network Providers or other entities that operate, support or manage Network Providers; physician-hospital organizations or physician organizations; Regional Health Information Organization (RHIOs), and others designed to enhance the overall health of the community.

Another area that needs further modification involves the requirement that hospitals can only donate technology to physicians on its own medical staff. 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 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. We believe that as long as other safeguards are in place to not otherwise impose barriers to compatibility, there is little risk of fraud or abuse. *(It should be noted that this area will also come into play as Donors incorporate selective donation criteria).*

Similarly, we believe a group practice should be able to provide technology to “independent contractors” providing services within the group or persons who are not physicians. In many cases, especially in emergencies, 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 sum, ACP strongly believes that in order to facilitate the distribution and implementation of electronic prescribing and EHR technology, the definition of Donors and Recipients should be drafted as broadly and inclusively as possible. It is unfair to permit certain Donors to provide technology, but restrict other providers from providing that same technology. We do not believe this was the intent of the Congress in drafting this provision, and therefore, recommend the OIG broaden its definition.

Selective Criteria (§1001.952)

The OIG is proposing 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 safe harbor does not preclude selection criteria that are based upon an indirect measure of business generated by the recipient (e.g. the total number of prescriptions written by a recipient of electronic prescribing hardware or software).

The College supports the need to exclude from the safe harbor 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 safe harbors. We suggest that the proposed rule include

incentives for donations covered by the safe harbor to promote donations to small (especially in rural and underserved) practices.

Proposed Pre-and-Post-Interoperability EHR Safe Harbors

The pre-interoperability and post-interoperability safe harbors would at least protect electronic health records software (that is, software that is essential to and used solely for the transmission, receipt, and maintenance of patients' electronic health records and electronic prescription drug information) and directly-related training services, provided that the software includes an electronic prescribing component. ACP requests that the elements covered by the safe harbor for EHRs be further clarified and expanded. More specifically, it is unclear from the proposed rule whether the donated costs of an EHR system operating within an Application Service Provider (ASP) model would be covered by the safe harbors. We seek clarification here.

Furthermore, it is unclear whether the "help desk" or the consultation that is routinely required with the implementation of an EHR system within a practice is covered by the proposed safe harbors. This service is vitally important to the success of implementation. It is also not clear whether clinical decision support technology (e.g., PIER) is included under the proposed safe harbors. We believe that this type of clinical decision support technology is an important element of any effective EHR system and should be protected.

Finally, the College strongly suggests that permitted donations be broadly expanded to include any equipment (especially hardware), item, information, right, license, intellectual property, software, training, education or service used for developing, implementing, operating or facilitating the adoption of EHR and other HIT and the electronic exchange of health information by physicians and other health care providers. In addition, we favor the OIG take the position requiring all donations meet or exceed the CCHIT-approved certification levels of functionality, interoperability, and security. We believe that the significant benefits of facilitating implementation of technology by including this broad category of CCHIT-certified donations within the safe harbor far outweigh the potential for increased abuse.

Value of Protected Technology

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 and the belief that a monetary limit is appropriate and reasonable to minimize the potential for fraud and abuse. First, we do not believe the risk for fraud and abuse is high and, more importantly, we believe that setting such limits would unnecessarily discourage potential Donors from providing technology.

The College questions the need for caps or aggregate limits to be placed on donated technology to meet the requirements of the 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. It also should be noted that donation value involves many other variables that the OIG should consider. For instance, there are fees for software licenses, IT support and training, processing, implementation, hardware, connectivity, and other elements. So, if the OIG is inclined to adopt a cap or aggregate limitation, we urge consideration of all the expenses (initial and ongoing) involved.

While we recognize the OIG's fraud and abuse concerns, we believe the proposed rule already contains sufficient protections that alleviate the need for a cap or aggregate limits. The placement of a cap or aggregate limitations would only serve to stifle the implementation of electronic prescribing and EHR technology. We are particularly concerned that a cap, without proper consideration of all the variables, will significantly disadvantage smaller practices that need the most financial assistance. We, therefore, do not believe a cap is warranted or necessary at this time.

Definitions of 'Interoperability' and 'Electronic Health Record'

ACP supports the OIG's use in the proposed rule of "interoperability" as "the ability of different operating and software systems, software applications, and networks to communicate and exchange data in an accurate, secure, effective, useful, and consistent manner." We believe this proposed language sufficiently defines the term.

The College suggests, however, that you reconsider the use of the term "electronic health record (EHR)." This term, as used in the proposed rule, is inconsistent with terminology used within the information technology industry and, its use to refer to several different concepts, is confusing to the reader. An EHR typically refers to the broad concept of the sum total of all the health care data that exists regarding an individual within the electronic universe. This may include an individual's personal health record, their history of medication use stored by a drug plan, medical records electronically stored by their primary physician, electronically stored imaging results stored in the local hospital etc. An EHR system refers to any system (e.g., e-prescribing, electronic medical record, personal health record) that is a component within the individual's EHR. An electronic medical record (EMR) system typically refers to patient-centric, electronically maintained information about an individual's health status and care that focuses on tasks and events directly related to patient care, and is optimized for use by clinicians. It is also limited in scope to the continuum of care within a single clinical delivery system. This EMR system definition is based upon a definition offered by the Gartner Consulting group for a computer-based patient record (CPR). In most instances throughout the proposed rule, we believe you are technically referring to an EMR system rather than an EHR, however, the final rule should make a clarification.

Community-Wide Health Information Systems

ACP strongly believes that a safe harbor for a community-wide health information system is desperately needed. In June 2004, ACP commented on the Phase II, Stark exception of the need for the Anti-Kickback Statute to have identical protections. Because community-wide health

information systems do not currently exist, maximum flexibility should be allowed to foster their development and interoperability among systems should be encouraged.

Specifically, ACP recommends that OIG adopt and incorporate the following guidance defining a “community-wide health information system:”

“Community-wide health information system shall include any health-information system that is designed and implemented by a community of interested providers and practitioners for the benefit of the patients they serve or for the more efficient administration of the health care system. Such communities may be formed based on a metropolitan statistical area, a health professional shortage area, a virtual community, a community of interest (*i.e.*, concerning specific disease states), or a hospital’s geographic area (defined as the lowest number of contiguous postal zip codes from which the hospital draws at least 75% of its inpatients), or other communities that are either geographically or virtually connected.

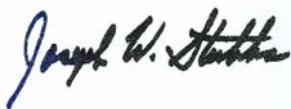
Additionally, we recommend the OIG work with CMS to clarify that access to a system may be constrained by criteria necessary for the development of the system and that entities have the discretion to provide such information technology or services, as long as the entity does not take into account the volume or value of services.

CONCLUSION

While we commend the OIG for submitting a proposed rule allowing the promotion of electronic prescribing and electronic health records, we strongly urge the OIG and CMS to make the necessary clarifications and promulgate the final rule as expeditiously as possible. Donors and Recipients need to have the necessary comfort to engage in these types of arrangements and the final rule should do nothing to discourage such engagements.

Again, ACP greatly appreciates this opportunity to comment on the proposed standards. Please do not hesitate to contact Neil Kirschner, Ph.D., Senior Associate, at (202) 261-4535 and nkirschner@acponline.org or Patrick Hope, Esq., Legislative Counsel, at (202) 261-4541 and phope@acponline.org if you have any questions regarding these submitted comments.

Sincerely,



Joseph W. Stubbs, MD, FACP
Chair, Medical Service Committee