June 10, 2013

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1454-P
P.O. Box 8013B
Baltimore, MD 21244-8013

Re: CMS-1454-P: Medicare Program: Physicians' Referrals to Health Care Entities with which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements

Dear Administrator Tavenner,

The College of American Pathologists ("CAP") appreciates the opportunity to respond to the Centers for Medicare & Medicaid Service's ("CMS") proposed rule amending the physician self-referral law's ("Stark Law") exception concerning donation of electronic health records items and services ("EHR"). CAP is a medical society serving 18,000 physician members who practice anatomic and/or clinical pathology and the global laboratory community. The College is the world's largest association composed exclusively of board-certified pathologists and is the worldwide leader in laboratory quality assurance. The CAP advocates accountable, high-quality, and cost-effective patient care. The CAP's Laboratory Accreditation Program is responsible for accrediting more than 7,000 clinical laboratories worldwide.

This comment letter is offered as a companion to comments submitted to the Department of Health & Human Services' Office of Inspector General ("OIG") related to its "almost identical changes" to the anti-kickback statute's electronic health records safe harbor. (78 Fed. Reg. 21308, 21310 (Apr. 10, 2013).) We are mindful that CMS "may consider comments submitted in response to OIG's proposed rule" because of the "close nexus" between CMS' proposed rule and OIG's proposed rule. (*Id.*) Nevertheless, we comment separately to offer CAP's full support for CMS' proposal to limit the scope of protected donors under the EHR exception to the Stark Law to exclude "laboratory companies." (*Id.* at 21312 ["we are considering excluding laboratory companies from the scope of permissible donors"].) We are also attaching for reference our comments to OIG regarding the EHR safe harbor submitted in 2009 and 2011 as part of OIG's annual solicitation required under the Health Insurance Portability and Accountability Act.

INTRODUCTION

We are pleased CMS is proposing to limit the scope of protected donors under the EHR exception to exclude "laboratory companies" and urge CMS to adopt this proposed rule excluding laboratories and pathology practices that provide anatomic and/or clinical laboratory services[1].

[1] While the limitation in the proposed rule is to "laboratory companies," for clarity's sake, the concerns and abuses extend to pathology practices and providers not only of clinical laboratory tests such as urinalyses and rapid strep tests, but also to anatomic pathology services that involve analysis of tissue or other human specimen usually taken during a surgical procedure. Pathology practices and laboratories that provide clinical and/or anatomic pathology services would need to be included under the ambit of "laboratory companies" and subject to exclusion from the exception.

As you may know, CAP has objected to the inclusion of pathology practices and laboratories that provide anatomic and clinical pathology services as protected donors since the EHR exception to the Stark Law was first promulgated. As discussed below, these objections arise from the abusive practices including functional lock-ins embedded in the donated EHR preventing full interoperability and access to donated EHR that our members are facing in the marketplace.

Without this limitation, the extension of the safe harbor beyond 2013 raises grave concern throughout the laboratory community, including CAP and its member pathologists. Excluding providers of anatomic pathology and clinical laboratory services from the EHR donation exception poses no risk of inhibiting the adoption of interoperable electronic health record technology. Should CMS finalize its proposal, significant incentives would remain for providers to adopt EHR and those with a vested interest in the full continuum of care – as opposed to a limited set of services such as anatomic and clinical pathology – would continue to be able to make donations that ultimately could benefit patient care.

ESCALATION IN ABUSIVE PRACTICES

The divergence between current laboratory EHR donation practices and those originally contemplated and intended under the EHR exception to the Stark Law is significant. As time marches on and laboratories remain protected donors, there is a persistent and widening gap between practical experience and the way the EHR donation exception was intended to operate. The surge in abusive practices fueled in large part by the meaningful use rule continues to escalate. With heightened expectations that the EHR exception will be extended, certain abusive practices by physician practices have become even more egregious. Indeed, our members report that the volume of requests for donations from providers of laboratory and pathology services has escalated, as have the increasingly unsavory tactics employed.

The typical pattern reported by our members involved an EHR vendor marketing its products. The vendor produces an estimate for a new EHR system for potential physician clients. The vendor then encourages such potential clients to approach the pathology practice/laboratory to which it sends its specimens to have that practice/laboratory "pay for the system," meaning 85% of the cost of the system, in accordance with the EHR exception. Pathology practices and laboratories have shared that not only are they approached with an estimate from the EHR vendor, but they are told that another laboratory has agreed to pay for the EHR and that the ordering physician will switch referrals to the laboratory that agrees to provide the EHR if the practice or laboratory does not agree to meet or exceed the offer. In several instances, the ordering physician that requests the EHR donation is almost apologetic for the nature of his or her approach and for reducing the decision to strictly monetary considerations, rather than the quality of care and longstanding satisfactory professional relationship. The decision is based solely on which pathology practice or laboratory will foot the bill rather than continuity of care even where chronic conditions are involved or physician and patient satisfaction with quality of services provided.

The increasingly egregious scenarios of which our members have become aware involve the following:

- Potential Cherry-Picking: In given geographies (some dense with Medicare beneficiaries), certain ordering physicians are targeted as EHR recipients by certain laboratories based on volume and value of clinical and/or anatomic pathology services ordered. Those same laboratories have little interest in donating EHR to ordering physicians who generate fewer or less costly orders for laboratory services.

- Post Donation In-Sourcing: Laboratories in a few markets have apprised CAP that EHR donations are being made to ordering physicians only to have them in-source their laboratory services (*i.e.,* establish a self-referral arrangement in their practice) within months of receiving the donated EHR. The timing of the donation so close to the in-sourcing makes it almost impossible that the planning for the in-sourcing was not already well underway when the donation was made. These situations enable ordering physicians to avoid bearing the full cost of the EHR when they discontinue use of an outside laboratory and bring the specimen testing into their own in-house self-referral arrangement just after receiving the donation.

Although not new, arrangements as a condition of doing business (receiving pathology specimens) with the EHR recipient physicians continue and seem to have become even more blatant. Members who have been approached for donations indicate that such donations are clearly presented as a condition of continuing to receive, shift or increase specimens. Although the agreement memorializing the arrangement does not expressly state that referrals are conditioned upon entering into a financial relationship in flagrant violation of the Stark Law, the stipulation is clearly and unambiguously verbalized.

Regardless of the scenario, the inclusion of pathology practices and laboratories as potential donors under the exception negatively affects access to health care services, quality, competition, cost to the federal health care programs and utilization. While intended to encourage the adoption of EHR technology, including pathology practices and laboratories as protected donors has not provided a mechanism to effectively influence clinical decision making or improve the efficiency of health care delivery to patients. Unfortunately, EHR donations by pathology practices and laboratories often accomplish just the opposite of what was intended as a result of the functional lock-ins discussed below.

FUNCTIONAL LOCK-IN

As you know, the EHR exception requires that any software donated be interoperable to protect against donors who improperly attempt to create closed or limited EHR systems by offering technology that functionally or practically locks in business for the donor. (*See* 42 C.F.R. § 411.357(w)(2)-(3).) Unfortunately, technical interoperability has not proven to be an adequate safeguard against the donation of software that operates to lock-in referral sources. As noted in the proposed rule, "even when donated software meets the interoperability requirements of the rule, policies and practices sometimes affect the true ability of electronic health record technology items and services to be used to exchange information across organizational and vendor boundaries." (78 Fed. Reg. at 21312.) CAP is amongst those who have commented in the past to OIG and others that **laboratory-donated EHRs may appear to support the interoperable exchange of information on their face, but in practice, lead to data and referral lock-in by blocking competitors from accessing the donated EHR system. As such, the EHR exception is being used in the laboratory context to lock-in data and referrals and impede the free flow of information.**

Our members are seeing donated EHR software packages that appear to be interoperable but, in practice, do not function with the EHR systems of other providers. For example, some donated software contains several modules that may be customized for the physician practice or specialty and provide for other capabilities outside those protected under the safe harbor. The EHR software may also include a proprietary interface between modules and EHRs to automatically populate the patient's EHR with data from the modules, including the results of all laboratory tests.

Often times this functionality is specific to the donor and the interface component only functions properly if specimens are referred to the donor's laboratory. In these cases, the specimens are rendered inaccessible to other health care providers within the patients' continuum of care. In other words, **if a recipient physician uses a different pathology provider than the laboratory that donated the software, the practice is likely not able to access needed clinical and other patient information contained in the donated EHR,** reducing the efficacy of patient care, potentially necessitating duplicate testing and resulting in additional costs of manual entry into the patient's record rather than electronic data. The creation of these "walled gardens" is completely at odds with the goals of the exception and the safe harbor and other government initiatives to expand EHR and interoperability.

With new payment models and greater coordination of care, robust access to health information that is multi-directional and interoperable is essential. These models rely on the laboratory not being just a source of data. **To achieve population management that relies so heavily on laboratory data and pathologists' expertise in this area, pathologists will require easy access to patient data across the patient's EHR and other clinicians will require easy access to readable and actionable data from the laboratory.**

STATE ACTION TO ADDRESS ABUSIVE DONATION PRACTICES

Several state governments have already recognized the potential for abuse in allowing laboratories to donate EHR. Notably, in 2010, the New York State Department of Health ("NYSDOH"), citing its awareness of abusive business practices, confirmed that clinical laboratories operating in New York State could not donate EHR to physicians. New York State found the offer of new EHR and software packages to be an inducement for practitioners to refer patient specimens for testing, resulting in financial benefit conferred to the practitioner. NYSDOH expressed concern about this financial benefit rather than quality, timely access to results or the specific needs of the patients influencing practitioners' choice of laboratory. NYSDOH concluded that the arrangements had the potential to adversely impact competition, reduce quality of services, and risk potential overutilization of health care services, resulting in unnecessary increased overall health care costs.

As recently as March 2013, a total of 7 states have either prohibited or limited the EHR donations of laboratories and pathologists under their state laws. The six additional states are Missouri, New Jersey, Pennsylvania, Tennessee, Washington State, and West Virginia.[2] A complete library of those state's opinions and/or guidance can be found on CAP's website at EHR Donation State Guidance and Opinion Letters.

[2] See: Rachel Bloch, State of New York Department of Health and Betty Kusel, State of New York Department of Health, letter to Laboratory Owner/Operator, 27 September 2010.
Dennis P. McDonough, MPH, New Jersey Clinical Laboratory Improvement Service, letter to Barry R. Ziman, College of American Pathologists, 16 March 2011.
Linda Lemke, Missouri Assistant Attorney General, opinion letter to Representative Chris Kelly, Missouri House of Representatives, 14 June 2011.
Robert C. Knittle, State of West Virginia Board of Medicine, letter to Kimberly A. Gyure, West Virginia Association of Pathologists, 9 July 2012.
Martin Rainowski, MA, Pennsylvania Department of Health, letter to Debbie Faesel, Pennsylvania Association of Pathologists, 18 August 2011.
Hon. Robert E. Cooper, Tennessee Attorney General, Opinion Number 13-16, March 4, 2013

CONCLUSION

We urge CMS to take the opportunity to re-balance promotion of EHR adoption with fraud and abuse prevention by removing providers of anatomic and clinical pathology from the scope of protected EHR donors. Not only would removing pathology practices and laboratories from the scope of protected donors put an end to the abuses described above, but it should also reduce costs to the federal health care programs by reducing overutilization resulting from the self referral incentive, implicit and in many instances, explicit to the recipient of the EHR system.

The College is pleased to have the opportunity to respond to CMS' proposed rule and appreciates CMS' consideration of our comments. Any questions regarding CAP's comments can be directed to Sharon L. West, JD, Director of Economic and Regulatory Affairs at 202-35407112 or swest@cap.org.

Sincerely,

Gerald R. Hanson, MD, FCAP
Lead, Regulatory Compliance Work Group
Economic and Regulatory Affairs Committee

Attachments: OIG 2009 and 2011 EHR Safe Harbor Letters

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February 17, 2009

Daniel R. Levinson
Inspector General
Office of Inspector General
Department of Health and Human Services
Cohen Building
330 Independence Avenue S.W.
Washington, DC 20201

Attention OIG-113-N, Room 5541

Dear Mr. Levinson:

The College of American Pathologists (CAP) appreciates the opportunity to respond to the Office of Inspector General's (OIG) solicitation on development of new and modification of existing safe harbor provisions under the Federal anti-kickback statute. The CAP is a national medical specialty society representing more than 17,000 physicians who practice anatomic and/or clinical pathology. CAP members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals and federal and state health facilities. CAP's response focuses on the safe harbor for electronic health items and services under 42 U.S.C § 1001.952(y) and how its impact on access to health care services, quality, competition, cost to Federal health care programs and overutilization differs from that intended under the safe harbor.

Background:

As you know, under the Federal anti-kickback statute, 42 U.S.C. §1320a-7b(b), any knowing and willful solicitation or receipt of remuneration, directly or indirectly, overtly or covertly in exchange for referring an individual to a person for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program. Those transactions where any one purpose of the donation is to induce Medicaid or Medicare referrals are violative of the Federal anti-kickback statute even if the transaction is for other legitimate business purposes. Given the breadth of the statute's scope and to promote the rapid and widespread adoption of an open, interconnected and interoperable health information technology system through

legitimate transactions not intended to induce referrals, a safe harbor was created in August 2006 for EHR items and services. The intent of the safe harbor was to encourage the adoption of EHR technology to help improve the quality of patient care and efficiency in the delivery of health care to patients, without protecting arrangements that hinder marketplace competition, serve as marketing platforms, or are mechanisms to influence clinical decision-making inappropriately. The College commends OIG and Congress for recognizing the importance of moving toward an interoperable, nationwide health information technology infrastructure through the adoption of this safe harbor exception.

"Solicitation of New or Revised Safe Harbors":

The CAP has become aware of abusive business practices that are afforded protection under the safe harbor but that run contrary to its intent. Specifically, commercial laboratories are offering EHR software packages as an inducement for physician practices to refer patients including those enrolled in Federal health care programs when fulfillment of the requirements of the safe harbor for such packages is questionable, practically speaking. The result is financial benefit conferred to the physician practice under such questionable arrangements influencing the physicians' medical decision-making and choice of provider rather than quality, access or the needs of patients and other providers who may need to access patient records electronically. As such, these arrangements adversely impact competition among health care providers, reduce quality of services, and risk potential overutilization of health care services (duplicate testing) resulting in unnecessary increased costs to Federal health care programs. As such, CAP urges OIG to exclude these arrangements from the safe harbor exception because the intent of the donor is to obtain referrals, including those for Medicare and Medicaid pathology services through the donation of EHR software and other items and services for the reasons set forth below.

Generally, in transactions such as those referenced above, the donated software package may include electronic health record technology with several modules that may be customized for physician practice or specialty and provide for other capabilities outside of those protected under the safe harbor. The EHR software may include a proprietary interface between the modules and electronic health records to automatically populate the patient's health records with the data from the modules, including the results of all laboratory tests amongst other features. The EHR safe harbor requires that the software donated must be "interoperable" to protect against donors who improperly attempt to create closed or limited electronic health record systems by offering technology that functionally or practically locks in business for the donor. 71 Fed. Reg. at 45122. In this situation, the EHR software package donated appears to be "interoperable" theoretically but does not function with software packages and EHR systems of other providers who need to access clinical information contained in the records of the donated software. The interface component is specific for the donor and functions only if specimens are referred to the donor's lab rendering them inaccessible to other health care providers within patients' continuum of care.

Although the contract between the recipient physician practice and the donor does not expressly mandate Medicare and Medicaid referrals of business and on its face may be consistent with the requirements of the EHR safe harbors, the stipulation is implicit in the arrangement because the EHR software interface can only be used for specimens sent to the donor's laboratory. If a recipient physician practice uses a different pathology provider than the laboratory who donated the software, the practice likely will not be able to access needed clinical and other patient information contained in the donated EHR reducing the efficacy of patient care, potentially necessitating duplicate testing and resulting in additional costs of manual entry into the patient's record rather than electronic data. In addition to the implicit stipulation, although receipt of EHR although not memorialized as a condition of doing business with the donor in the written contract, it is conveyed in conversations between donor salesperson and recipient physician practice. Though the evidentiary value of such conversations is minimal, the change in practices pre- and post-donation should fulfill the "one purpose" test applied to determine anti-kickback statute violations. Unequivocally, the financial benefit from this exchange ties the referrals from the recipient physician practice to the donor providing remuneration for Federal health care business that does not conform to the EHR safe harbor and therefore in practice, violates the federal anti-kickback statute.

To achieve the objectives of interoperability, HIT systems must enable data to flow smoothly and reliably among health care providers' differing HIT systems. Currently, most electronic health care data are trapped in "silos" due to fragmented systems that are not functionally interoperable. The result is fragmented delivery of care with incomplete interventions that are frequently duplicative, inefficient, and uncoordinated, resulting in missed opportunities to use and rely on evidence-based medicine. An example of this care fragmentation occurs when the same laboratory services are ordered twice by two different physicians to diagnose and/or treat a patient for the same medical recurrence because both physicians cannot access the patient's lab records or care is delayed because one of the physicians cannot secure such records from the physician who initially performed the test. Finally, the safety of the patient may be put at risk when lab records for life threatening conditions are not transmitted or accessible to providers outside a specific provider's EHR system. This can occur even when the HIT system is deemed to be "theoretically" ***inter***operable because the silos create a "functional" ***in***operability.

The CAP asks that OIG reconsider its inclusion of laboratories within the electronic health record safe harbor category of protected donors. These arrangements do not promote widespread adoption and use of health information technology, as intended by the safe harbor, but instead promote fragmented care, duplicate testing, and a reduction in care coordination. In fact, many of our member laboratories have indicated that electronic access to records is even less effective than it had been prior to the adoption of the EHR safe harbor due to the impediments and perverse incentives that have resulted due to the permissibility of donated laboratory records under the current safe harbor. The potential for abuse and over-utilization is extremely high because of the existing profit incentive. Consequently, the CAP supports a modification to the safe harbor to remove laboratories from the category of protected donors.

The CAP also recommends that the OIG modify the safe harbor to state that a donor cannot tie the donation of software that qualifies under the safe harbor to the acceptance of non-qualifying technology, even if the additional technology is accepted at the recipient's cost. This condition would prevent a donor from offering qualifying software on the condition that the recipient purchase or license interfaces, upgrades, or modifications to the qualifying software that would functionally tie the recipient to the donor for the provision of some or all of the recipient's referrals for health care services, regardless of payer source for such services. In this case, a laboratory could not offer EHR software on the condition, express or implicit, that the recipient physician practice purchase or license additional features, software or interfaces from the donor.

The College of American Pathologists is pleased to have the opportunity to respond to OIG's solicitation on the safe harbor provisions of the Federal anti-kickback statute and appreciates your consideration of CAP's response. Any questions regarding proposed changes should be directed to Traci Bone at 202-354-7133 (tbone@cap.org).

Sincerely,

Jared N. Schwartz MD PhD FCAP

Jared N. Schwartz, MD, PhD, FCAP
President

February 25, 2011

Daniel R. Levinson, Inspector General
Office of Inspector General
Congressional and Regulatory Affairs
Department of Health and Human Services
Attention 01G-118-N, Room 5541
Cohen Building
330 Independence Avenue S.W.
Washington, DC 20201

Dear Mr. Levinson,

The College of American Pathologists (CAP) appreciates the opportunity to respond to the Office of Inspector General's (01G) solicitation on proposals and recommendations for development of new and modification of existing safe harbor provisions under the Federal anti-kickback statute. CAP is a national medical specialty society representing more than 17,000 physicians who practice anatomic and/or clinical pathology. CAP members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals and federal and state health facilities. In its response below, CAP focuses on the anti-kickback statute electronic health records (EHR) safe harbor; in particular, (i) the negative effects of laboratory EHR donations under the safe harbor on access to health care services, quality, competition, cost to Federal health care programs and overutilization, and (ii) the divergence between current laboratory EHR donation practices and those originally contemplated under the safe harbor.

Background

As you know, under the Federal anti-kickback statute, any knowing and willful solicitation or receipt of remuneration, directly or indirectly, overtly or covertly in exchange for referring an individual to a person for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program is prohibited. Those transactions where any one purpose of is to induce Medicaid or Medicare referrals are violative of the Federal anti-kickback statute even if the transaction is for other legitimate business purposes. In order to promote the rapid and widespread adoption of an open, interconnected and interoperable health information technology system through legitimate transactions not intended to induce referrals, a safe harbor was created in August 2006 for the donation of EHR items and services. The intent of the safe harbor was to encourage the adoption of EHR technology to help improve the quality of patient care and efficiency in the delivery of health care to patients, without protecting arrangements that hinder marketplace competition, serve as marketing platforms, or are mechanisms to influence clinical decision-making inappropriately. The College understands and appreciates the intent behind establishing mechanisms to promote an interoperable, nationwide health information technology infrastructure such as the safe harbor. Unfortunately, electronic health records donations currently sought from pathologists under the auspices of the safe harbor far from reflect this intent.

In recent months, CAP has witnessed a surge in seemingly abusive business practices reflected in requests received by its member pathologists and their practices for donations of EHR software

packages. At the same time, the State of New York, citing its awareness of abusive business practices, has confirmed that clinical laboratories operating in New York State may not donate electronic health records to physicians. In this response, CAP will detail the New York guidance, the latest abusive practices in play, and significant deviation between current practices and those intended at the time of safe harbor was developed. Based on these factors, CAP will recommend that laboratories no longer be protected donors under the EHR safe harbor.

New York Prohibition on Laboratory EHR Donation

The New York State Department of Health (NYSDOH) not only noted its concern regarding abusive practices, but went on to prohibit EHR donations by clinical laboratories late last year. In September 2010, the NYSDOH confirmed in writing to laboratory owners and operators, that clinical laboratories operating in New York State may not donate electronic health records to physicians. NYSDOH indicated in its communication that it had become aware of "abusive business practices." Specifically, NYSDOH cited the offer of new EHRs and software packages as an inducement for practitioners to refer patient specimens for testing, resulting in financial benefit conferred to the practitioner. NYSDOH also expressed concern about this financial benefit rather quality, timely access to results or the specific needs of patients influencing practitioners' choice of laboratory. It concluded that these arrangements have the potential to adversely impact competition, reduce quality of services, and risk potential overutilization of health care services, resulting in unnecessary increased overall health care costs. NYS DOH acknowledged that provision of EHR, software, and training that otherwise may be permitted under federal law is prohibited in connection with a laboratory's operating in New York State. NYSDOH's correspondence raises another aspect of these abusive practices through its implication that the provision of EHR technology by certain laboratories to practitioners has been at less than fair market value.

It is the very concerns NYSDOH cited as the basis for prohibiting EHR donations by clinical laboratories that give rise to the concerns CAP expresses in this response to OIG's solicitation and request for modification of the Federal anti-kickback statute so that laboratories are no longer protected donors under the EHR safe harbor. Without a prohibition similar to that of New York's at the federal level, abusive business practices and inducements to refer due to financial benefit to the practitioner remain as does adverse impact on competition, quality of services and risk of overutilization NYSDOH so effectively articulated in its September 2010 communication.

EHR Donation Requests

While CAP has in previous years expressed concerns regarding laboratory donations under the safe harbor to OIG, recent practices employed have become even more abusive as a result of other regulatory and financial influences currently in play. The scenario CAP member pathologists frequently share regarding recent requests received for them to donate EHR systems is that an EHR vendor shares an estimate for new EHR system with potential clients who are ordering physicians and encourages the ordering physicians to approach the pathology practice/laboratory to which it sends its specimens to have that practice/laboratory "pay for the system" (eighty-five percent (85%) of the cost of the system) in accordance with the safe harbor. The emphasis is on the ordering physicians near exclusive arrangements with pathology practices for the provision of laboratory services and the minimal amount of fifteen percent (15%) the ordering physician contributes in exchange for a new EHR system. Continuity of care or quality of historic services provided and patient satisfaction and access to services are for all intents and purposes disregarded. The focus then becomes on whoever will foot the bill for the system other than the 15% the ordering physician is required to contribute under the safe harbor. In some instances, it is even questionable whether the requesting practices do not already have interoperable EHR rendering the donation impermissible under the safe harbor.

The recent surge in such requests is fueled in large part by the Health and Human Services meaningful use rule now in effect. The rule implements the requirements of the Health Information Technology for Economic and Clinical Health (HITECH) Act, part of the American Recovery and Reinvestment Act (ARRA) enacted February 17, 2009 including the requirement that EHR/modules be certified. Not only is the certification requirement a factor, but also the financial incentives under the rule that have now taken effect and run through 2014 and in the longer term, the penalty that will be applied under the rule for not meeting meaningful use requirements effective 2015. These requirements while clearly designed to expedite EHR adoption have also served to increase not only the volume of EHR donation requests received by pathologists, but also the tactics employed and tone associated with such requests.

Although prohibited under the safe harbor, the donations, directly and indirectly and overtly as well as covertly, have been used to induce or reward the generation of referrals of individuals enrolled in Federal health care program and create inducements the anti-kickback statute seeks to avoid. OIG rightly so, noted in its August 2006 response to public comments that financial arrangements involving incentives in the form of health information technology do pose the same fraud and abuse concerns as other financial arrangements between parties in a potential referral relationship. A common theme to the scenarios CAP's member pathologists describe is that ordering physicians for whom they have long provided pathology services simply switch their referrals to a laboratory that has covered 85% of a new EHR system without even approaching the pathology practice in advance of the switch. Alternatively, the ordering physician approaches the pathology practice with the written estimate provided by the EHR vendor indicating that another laboratory(ies)have agreed to cover 85% of the cost of the system. The estimate is presented with the indication that the ordering physician will move its referrals for pathology services if the current provider of laboratory services does not also agree to cover 85% of the costs of the new system. These messages are conveyed without regard for the ordering physician's longstanding satisfaction with the effective delivery of laboratory services to Medicare beneficiaries or continuity of care particularly for those beneficiaries who may have chronic conditions necessitating ongoing pathology services.

In several instances, ordering physicians have expressly stated that turnaround times, access, satisfaction and quality of care provided under the longstanding relationship for pathology services have been superior and that the switch is being made solely to obtain the new EHR system at 15% of the cost of those items permitted under the safe harbor. In other instances, there is mention that the ordering physician will switch its referrals to the laboratory that pays for the new EHR system for a year or other contractually specified term. It then will re-establish its relationship with the pathology practice to which it previously referred given higher degree of satisfaction with that practice's quality, turnaround time and level of service overall. These factors directly address the factors OIG notes for consideration of modified safe harbor provisions, specifically regarding quality of services and access to health care services. When lengthier turnaround time for laboratory results occur under new arrangements with the laboratory donor of the new EHR, not only are quality and competition negatively impacted, but also access to services by Medicare beneficiaries who may have to wait longer for what could be very sensitive results.

Finally, regarding inducements for the referral of individuals enrolled in federal health care programs, we are told repeatedly of discussions between donors and ordering physicians that the EHR donation is a condition of doing business (receiving pathology specimens) with the ordering physician recipient. Because of the prohibition on so doing in the safe harbor, this quid pro quo is not contained in the written agreement that memorializes the donation required under the safe harbor, but may be an explicit oral agreement. Except for obvious changes in referral practices and volume, fully demonstrating violations of the statute to evidentiary satisfaction, is challenging in these instances absent further investigation. In the preamble to the 2006 final rule, OIG expressed concern about the potential for abuse involving EHR donations with several provider types including laboratory. As such,

OIG indicated its intent to monitor the situation and to "revisit" its determination that safe harbor conditions in the final rule were adequate for these provider types if abuses occur. As acknowledged above, monitoring to ensure compliance is not an easy proposition. As a result, arrangements that do not in practice conform to the safe harbor not only remain intact, but also have proliferated. For the aforementioned reason expressed by OIG and the abuses outlined above, we encourage investigation of certain specific arrangements. More importantly, we also urge revisiting the inclusion of laboratories as protected donors of the safe harbor.

Current Practices/Intended Safe Harbor Protection

CAP has become aware of an increasing number of abusive business practices that are afforded protection under the safe harbor, but that run contrary to its intent. In the preamble to the final rule, OIG appropriately so, acknowledged the hospital industry raised the need for safe harbor protection for arrangements involving technology other than just electronic prescribing. That hospitals seek such protection given their relationships, contractually and operationally, with physicians with whom they are transacting on a broad scale is understandable from the perspective of efficiency and ability to provide and access services across the full continuum of care. These arrangements provided what was perhaps an appropriate ground for donations under the EHR safe harbor. What is less understandable, though, is the application of safe harbor protection to non-hospital providers such as pathologists who do not have the same need or broad stake in providing a similar contribution or developing interoperable EHRs sufficient to warrant safe harbor protection. While CAP is supportive of the expansion of electronic health records and has advocated regarding the importance of electronic laboratory information particularly to facilitate coordinated care and reduce waste in the health care system, it remains concerned about breadth of the current safe harbor that subjects it to the same extent as hospitals.

As OIG noted in the preamble to the rule, certain providers and "suppliers of ancillary services such as laboratories would not have a comparable stake in advancing the goal of interoperable electronic health records for patients." In fact, as OIG indicated, its inclusion of these providers under the safe harbor raised concerns about abusive referral practices. CAP concurs completely with OIG's distinguishing laboratories from other donors in terms of stake in the process and overall objective. The safe harbor extends to functions far above and beyond those that may affect laboratory services and the care to patients based thereupon yet leaves laboratories responsible for the same percentage contribution as providers such as hospitals who have a far broader interest extending beyond those functions that impact pathology and the provision of laboratory services. That the safe harbor was temporary and is due to sunset at the end of 2013, per the preamble to the rule, adequately addressed OIG's concerns. The temporary nature of the safe harbor, though, seems to have permitted time for abusive practices, at least in the context of laboratory's status as the protected donors, to manifest rather than for interoperable EHR to expand absent fraud and abuse. For this reason, we urge OIG to re-balance promotion of EHR adoption with fraud and abuse prevention, the latter of which is not furthered by continuing to include laboratories as protected donors under the safe harbor.

In numerous instances, CAP member pathologists have offered to fund the cost of an interface between the laboratory's laboratory information system (LIS) and the ordering physician to facilitate electronic test ordering from the laboratory and receipt of laboratory results also in an electronic fashion as permitted under the Stark self-referral law. Ordering physicians, though, often reject this offer in favor of securing a full EHR through another donor under the anti-kickback safe harbor. The bright line test OIG sought to establish under the safe harbor focused on those individuals and entities with a substantial and central stake in patient's electronic health records seems may never have been fully applicable to donations by laboratories. This distinction becomes even more clear in recent years as more creative arrangements have emerged particularly with laboratory EHR donations and the financial and regulatory climate has changed. Amongst those climate changes is the broader recognition of the need to incentivize EHR adoption and substantial incentive opportunity available to

hospitals and physicians to obtain EHR technology under ARRA. This opportunity dramatically reduces, if not eliminates the need for donations to be covered under the safe harbor. At a minimum, it continues to raise concerns that a recipient could contribute a mere fifteen percent to the cost of an EHR system, yet pocket the incentive payment available under ARRA.

In closing, the CAP formally requests that OIG reconsider its inclusion of laboratories within the electronic health record safe harbor class of protected donors. Laboratory EHR donation arrangements permitted under the safe harbor do not promote widespread adoption and use of health information technology, as was intended, but raise concerns about access to health care services, quality, and cost to Federal health care programs and overutilization due to the referral incentive, implicit or explicit to the recipient of the EHR system.

The College of American Pathologists is pleased to have the opportunity to respond to OIG's solicitation on the safe harbor provisions of the Federal anti-kickback statute and appreciates your consideration of our response. Any questions regarding CAP's response can be directed to Sharon West at 202-354-7112 or swest@cap.org.

Sincerely,

Gerald R. Hanson, MD/SLO

Gerald R. Hanson, MD, FCAP
College of American Pathologists

cc: Sharon L. West, JD