February 25, 2010

Daniel R. Levinson, Inspector General
Office of Inspector General
Congressional and Regulatory Affairs
Department of Health and Human Services
Attention OIG-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 (OIG) 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