Good morning Madam Chairman and Members of the Subcommittee. I am Lewis Morris, Chief Counsel at the U.S. Department of Health and Human Services' Office of Inspector General (OIG). I appreciate the opportunity to discuss OIG's proposed safe harbors under the Federal anti-kickback statute for certain arrangements involving electronic health records technology.

The process of crafting these particular safe harbors requires OIG to balance the policy goal of advancing the use of health information technology with the objective of this important criminal statute: the elimination of potential financial conflicts of interest in the Federal health care programs. Working collaboratively with our government partners and considering the many constructive comments we received from industry stakeholders, we are in the process of developing rules that we believe will strike an appropriate balance.

Let me begin by stressing that the Inspector General shares Secretary Leavitt's commitment to the goal of fostering patient safety, quality of care, and efficiency in the delivery of health care through better and more widespread use of health information technology. Fully interoperable electronic health records systems will ensure that all patients will reap the benefits of the technology no matter where they receive their care. The promotion of this technology, including electronic health records, is among Inspector General Levinson's top priorities. In furtherance of this goal, OIG sought to lower perceived barriers to the adoption of health information technology by proposing anti-kickback safe harbors that would promote the adoption of open, interconnected, interoperable electronic health records systems, while safeguarding against undue risks of fraud and abuse.

Mindful that there are many possible approaches to such a safe harbor, we sought extensive public input on all aspects of our proposed rulemaking. The proposed safe harbors were published in the Federal Register on October 11, 2005 (70 Fed. Reg. 59015), and we received over 70 comments from hospitals, health systems, and other stakeholders. The safe harbors, if finalized, would protect certain arrangements under which hospitals and other specified donors furnish physicians and other specified recipients with free or below-market value electronic health records software and related training services.

My testimony begins with a summary of the Federal anti-kickback statute and a discussion of our longstanding concerns about arrangements involving the provision of free or reduced cost goods or services to potential referral sources. I will then discuss the provisions of our proposed safe harbor. I will not be addressing the proposed rulemaking developed by the Centers for Medicare & Medicaid Services (CMS) to create a comparable exception under section 1877 of the Social Security Act (the Act), commonly known as the "Stark" law. However, I assure you that we worked closely with CMS to

ensure as much consistency between the two proposed rulemakings as possible, given the differences in the underlying statutes. It is our intent for the final rules to be similarly consistent. I am not in a position to represent the views of the Department of Justice, which has separate law enforcement authority for the Federal anti-kickback statute.

THE ANTI-KICKBACK STATUTE AND THE RISKS POSED BY FREE GOODS AND SERVICES

The Federal anti-kickback statute is one of several statutes that, broadly speaking, seek to eliminate potential financial conflicts of interest from the Federal health care programs so that health care decisionmaking is untainted by inappropriate financial influence. Our Federal health care programs, including Medicare and Medicaid, rely on physicians and others to order or select only medically necessary items and services and to refer patients to providers, suppliers, and products based on the patients' best medical interests. Financial incentives linked to referrals create risks of, among other problems, over-utilization of items or services, increased costs to the Federal programs, corruption of medical decisionmaking, and unfair competition.

The anti-kickback statute, section 1128B(b) of the Act, is a criminal statute that prohibits the knowing and willful offer, solicitation, payment, or receipt of remuneration to induce or reward the referral of any business payable by a Federal health care program. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to induce or reward referrals. Parties that violate the statute may be subject to criminal, civil, or administrative penalties. OIG has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. Compliance with a safe harbor is voluntary, and failure to fit squarely in a safe harbor does not mean an arrangement is per se unlawful. Rather, the arrangement must be evaluated on a case-by-case basis under the anti-kickback statute.

OIG enforces the anti-kickback statute in partnership with the Department of Justice. Unscrupulous parties pay kickbacks in a variety of ways, and these schemes evolve over time. Often kickbacks are disguised as otherwise legitimate payments or are hidden in business arrangements that appear, on their face, to be appropriate. In our experience, the provision of free or below-market goods or services to actual or potential referral sources (whether physicians or other individuals and entities) presents a heightened risk of fraud and abuse. Simply put, the free or reduced price goods or services may be used as a vehicle to disguise an unlawful payment for referrals of Federal health care program business. Because physicians are effectively the gatekeepers for a substantial amount of Federal health care dollars, the programs and their beneficiaries are placed in jeopardy when a physician's ability to perform this crucial role is potentially corrupted by the

inappropriate influence of a kickback. This risk grows as the value of the free goods and services increases.

Recent kickback cases have involved referral payments in the form of free office space, free equipment, free office personnel, free drugs or other supplies, inflated or sham consulting contracts, and travel and entertainment to physicians by hospitals, pharmaceutical companies, and laboratories. In our enforcement experience, arrangements that result in avoided overhead expenses (such as, free support staff, free rent or equipment, or reduced administrative expenses) can form the basis of a kickback. These arrangements provide a clear economic benefit to the recipient in the form of savings. Unfortunately, the illegal use of free goods and services to reward referrals has a long history. For example, we addressed the issue of free computers to potential referral sources in the preamble to the original final safe harbors published in 1991. The preamble states:

> In some cases the computer can only be used as part of a particular service that is being provided, for example, printing out the results of laboratory tests. In this situation, it appears that the computer has no independent value apart from the service that is being provided and that the purpose of the free computer is not to induce an act prohibited by the statute. . . . In contrast, sometimes the computer that is given away is a regular personal computer, which the physician is free to use for a variety of purposes in addition to receiving test results. In that situation the computer has a definite value to the physician, and, depending on the circumstances, may well constitute an illegal inducement. 56 Fed. Reg. 35952, 35978 (July 29, 1991).

We have provided similar guidance with respect to, for example, the provision of free phlebotomists and testing supplies by laboratories to physician offices. Similarly, the provision of free or below-market electronic health records technology by a hospital to a physician in the position to refer Federal program business, depending on the circumstances, could violate the statute.

THE MMA SAFE HARBOR

In connection with the new Part D outpatient prescription drug program, in section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Congress directed the issuance of a limited safe harbor under the anti-kickback statute for donations by specified donors to specified recipients of hardware, software, or information technology and training services "necessary and used solely" for the electronic prescribing of drugs. The safe harbor parameters established by Congress evidence a careful balancing of the policy goal of promoting electronic prescribing with the need to prevent fraud and abuse. We have proposed a safe harbor for electronic prescribing technology, as mandated by Congress.

Hospital and other industry stakeholders, as well as government policymakers, expressed a concern that a safe harbor limited to electronic prescribing technology would be neither useful nor practical. They asserted that advancing the goals of increased patient safety and quality and better efficiency in health care delivery would require corresponding safe harbor protection for free or below-market electronic health records technology. These stakeholders expressed the view that without broader safe harbor protection for donations of electronic health records technology, hospitals and others would not provide free or very low cost electronic health records systems to physicians in their service areas.

THE OIG'S PROPOSED SAFE HARBOR FOR ELECTRONIC HEALTH RECORDS SOFTWARE AND RELATED TRAINING SERVICES

In response to the call for broader safe harbor protection, OIG proposed two additional safe harbors for electronic health records arrangements and solicited comments on how to balance the goal of promoting the adoption of electronic health records with the objectives of the anti-fraud statutes. As I have explained, the provision of free electronic health records technology poses all the usual risks associated with the provision of free goods and services to referral sources. If one purpose of the provision of free or below-market priced hardware, software or technical support is to induce or reward referrals of Federal health care program business, the anti-kickback statute is implicated. Moreover, there is a risk that a donor will use offers of free technology to induce recipients to change loyalties from other providers or plans to the donor. Notwithstanding the potential for abuse, in the interest of advancing the important public policy objective of widespread adoption of electronic health records, OIG proposed two safe harbors for arrangements involving electronic health records software and related training services: one to apply before the Secretary adopts interoperability standards and one to apply after. Dr. David Brailer is here today, and he is better able to discuss these standards in detail. I am going to focus my remarks on the proposed "post-interoperability" safe harbor, because that proposal appears to be of greater interest and relevance to industry and government stakeholders.

In developing the proposed safe harbor, OIG sought to propose conditions that would create a balance between protecting beneficial arrangements while safeguarding against the undue risk of fraud and abuse. As described in more detail in the notice of proposed rulemaking, the proposed safe harbor would protect donations of electronic health records software and related training services, provided that the protected software includes an electronic prescribing component. The proposed safe harbor would require that the software be essential to and used solely for the transmission, receipt, and maintenance of patients' electronic health records and electronic prescription information. We also solicited comments on whether additional software applications should be protected if electronic health records and electronic prescribing remain core functions. We would not protect donations of technology that is used by a recipient solely to conduct personal business or business unrelated to the recipient's medical practice, because there would be a high risk of abuse and no promotion of electronic health records adoption.

The proposed safe harbor would protect the same donors and recipients that Congress included in the MMA safe harbor for electronic prescribing arrangements. Accordingly, protected arrangements would be limited to: (1) hospitals donating to members of their medical staffs, (2) group practices donating to members of the practice, and (3) prescription drug plan sponsors and Medicare Advantage organizations donating to network pharmacists and pharmacies and to prescribing health care professionals. We believe these entities are the appropriate focus for safe harbor protection because they have a direct and primary patient care nexus, they play a central role in the health care delivery infrastructure, and they are well-positioned to promote widespread use of electronic health records technology that is open and interoperable. Notwithstanding, we solicited public comment on whether other donors and recipients should be included in this safe harbor.

To promote the objectives of an interoperable health records system, the proposed safe harbor would require that protected software be certified in accordance with product certification criteria for interoperability adopted by the Secretary. We believe that donations of technology that meets uniform interoperability standards for electronic health records adopted by the Secretary, as well as product certification criteria to ensure that products meet those standards, will help preclude unscrupulous donors from using closed or isolated systems to tie recipients to particular providers or suppliers. In light of the enhanced protection against some types of fraud and abuse that would be offered by certified, interoperable systems, we indicated that we are considering giving donors some additional flexibility in selecting recipients of the technology. Specifically, we indicated that we are considering permitting donors to use selective criteria for choosing recipients, provided that neither the eligibility of a recipient, nor the amount or nature of the items or services provided, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. Examples of criteria that would be appropriate under this proposed condition might include a determination based on the total number of hours that the recipient practices medicine or the size of the recipient's medical practice. Consistent with our objective of minimizing the risk of abuse, donors could not select recipients based on the number or value of Medicare-payable items or services referred to the donor. We expect that this approach would allow donated electronic health records technology to be provided to recipients most likely to use it, without protecting problematic direct correlations with referrals.

This approach to selective criteria, if adopted, would be a deliberate departure from other safe harbors that prohibit any determinations that take into account, directly or indirectly, potential referrals or other business generated between the parties. This proposed approach responds to the unique policy considerations surrounding electronic health records systems and the Department's goal of encouraging their adoption. Outside the context of electronic health records, as specifically addressed in the proposed rule, both direct and indirect correlations with Federal health care business remain highly problematic under the anti-kickback statute.

Finally, to reduce the risk of fraud and abuse, we indicated that we are considering capping or other otherwise limiting the aggregate value of the donated technology. In

this regard, we solicited public comment on a range of possible options for structuring such a limit, as well as on the retail and nonretail costs of the technology. We also indicated that we would require full transparency of arrangements through complete and appropriate documentation.

CONCLUSION

It is important that any safe harbor for electronic health records arrangements promote open, interconnected, interoperable electronic health records systems that help improve the quality of patient care and efficiency in the delivery of health care to patients, without protecting arrangements that serve to influence inappropriately clinical decisionmaking or tie physicians or other referral sources to particular providers or suppliers. We were mindful as we drafted the proposed rulemaking that there are several possible approaches to this safe harbor and that we did not have full information on all relevant aspects of such arrangements. For that reason we used the rulemaking solicitation as a platform to solicit public comments on virtually all aspects of the proposed rulemaking. The health care stakeholders responded by providing substantive comments on a wide range of issues. We are in the process of reviewing and considering those comments and evaluating options for the final rulemaking. Ultimately, our goal is to achieve an appropriate balance between fostering the adoption of beneficial electronic health records systems and preventing fraud and abuse in the Federal health care programs.

This concludes my prepared statement. I would be pleased to answer any questions you or Members of the Subcommittee may have.