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December 5, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

Re: CMS-1303-P; Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements; Proposed Rule.

Dear Dr. McClellan:

The American Hospital Association (AHA), on behalf of its 4,800 member hospitals, health care systems, other health care organizations, and 33,000 individual members, appreciates the opportunity to comment on the proposed rule outlining an exception to the Physician Self-Referral, or "Stark," regulations. These regulations, together with the anti-kickback regulations, pose a significant barrier to hospitals and physicians working together to realize the promise of health information technology (IT) to improve the coordination and quality of patient care.

The proposed rules seek to give hospitals more flexibility with protections from prosecution under the Stark law when they provide physicians on their medical staffs with certain IT items and services under three scenarios:

- Provision of resources for e-prescribing;
- Provision of electronic health record (EHR) software and directly-related training in advance of national standards for interoperability; and
- Provision of EHR software and directly-related training after national standards for interoperability have been adopted and incorporated into a certification process.

The proposed rules define the protected arrangements, including those between hospitals and members of their medical staff who routinely furnish services at the hospital. Conditions include limitations on the covered technology, a requirement that the donated items are not "technically or functionally equivalent" to items the recipient already has, and documentation requirements. The exception also states that the donor must not consider the volume or value of referrals or other business generated between the physician and the donor, and must comply with the anti-kickback statute.

The AHA appreciates the initial steps taken by the Centers for Medicare & Medicaid Services (CMS) in setting out these proposed rules. However, the AHA urges CMS to broaden the scope of these exceptions. Under the proposed rules, hospitals still will risk penalties and will not feel confident enough to work with physicians to help them build their IT capacity and expand the exchange of health information for clinical care.

Our comments first address larger issues, such as the policy goals, the separation of pre- and post-interoperability phases, the need for a parallel anti-kickback safe harbor, and the Secretary's breadth of authority to propose an exception; and then turn to specific aspects of the proposed regulations.

Policy goals

The President has set forth a bold goal of electronic health records for all Americans by 2014. However, many physicians are wary of IT investment because of its costs and risks, and because their staffs lack experience. Some hospitals' IT systems are more advanced than those of the physicians practicing in their community. These hospitals also have greater access to capital for financing the considerable costs – recent estimates put the overall price tag at $156 billion – of health IT. They also tend to have larger IT staff, and could lend that expertise to help physician offices adopt EHRs.

While the use of EHRs within hospitals and physician offices promises to improve quality of patient care, even greater benefits can be obtained by sharing information across health care providers so that, for example, emergency department staff have access to medical histories, and primary care physicians can know what medications were given during an inpatient stay. As noted in the proposed rule, greater sharing of information has many benefits, including improved continuity of care, decreased need for repeat tests, and safer, higher quality care. It also would improve hospitals' ability to report on quality. Hospitals are actively pursuing quality improvements and need the flexibility to use the tools that will improve quality and safety. This includes working with physicians to implement and connect IT systems.

Not all hospitals are in a position to help physicians adopt EHR, but those that are must be given the flexibility to do so. The Stark law imposes severe penalties on hospitals and physicians that violate it, and the fear of violating it is inhibiting progress in IT adoption. Stark prevents physicians from referring Medicare and Medicaid patients to organizations in which they have a financial interest; this includes inpatient and outpatient care. It is a "strict liability" statute and no element of intent is required for prosecution. Violators also are subject to significant civil money penalties if they knew or should have known that their referrals were prohibited. Stark law violations also may be pursued as violations of the federal False Claims Act.

Providing an exception to the Stark rules for e-prescribing and EHRs will accelerate physician use of health IT. Patients will benefit from wider IT use and better integration of hospital and physician information systems, resulting in improved coordination of care, reduced medical

errors, and reduced repeat tests. The President and others in the Administration have noted the urgency for progress in this area.

While acknowledging the important policy goals articulated by the President and others in the Administration, the proposed rule still considers IT hardware, software and services donation to be a potential vehicle for fraud and abuse. However, the kinds of relationships hospitals form with physicians for IT are different from other relationships that may raise fraud and abuse concerns, where physicians would receive financial benefit each time they referred a patient to, for example, a laboratory in which they had a financial stake. Furthermore, the original Stark legislation also was motivated by a desire to decrease unnecessary and duplicative testing and services. An integrated EHR that allows hospitals and physicians to share test results and other clinical information should further that goal. Thus, a Stark exception that would encourage and facilitate physician adoption and use of EHRs brings about significant benefits for patients while posing minimal, if any, risk of fraud and abuse. Failure to provide a workable Stark exception risks losing an important opportunity to increase physician use of EHRs and clinical information exchange, which would improve quality of care for all patients.

Pre- and post-interoperability periods

The proposed rule outlines two distinct EHR exceptions – one in the pre-interoperability period and one post-interoperability. The demarcation between these periods would be the adoption of EHR certification criteria by the Secretary, including interoperability criteria. The exception would be slightly broader in the post-interoperability period.

The proposed rule discusses the progress the Certification Commission on Health Information Technology (CCHIT) has made toward developing a model certification process under a grant from the Office of the National Coordinator for Health Information Technology. Nevertheless, a certification process does not yet exist, and many questions remain. The level of interoperability that currently can be certified is limited, given the current lack of agreement on standards. The operational questions of how products will be certified have not been answered, nor have questions about how widespread certification will be, what it will cost, and when it will be achieved. CCHIT has made considerable progress on developing a model process, but adoption of criteria and a certification mechanism by the Secretary of Health and Human Services (HHS) may take considerable time.

While hospitals share the goal of achieving interoperability, tying the broader Stark exception to a certification process that does not yet exist will not provide the clarity or flexibility needed for hospitals to feel comfortable. This approach also goes against the policy purpose of spurring adoption today and the need for urgent action. Allowing for more rapid dissemination of EHRs to physician offices, though, could increase the demand for interoperability. As physicians get assistance in implementing EHRs and discover their usefulness, they will also push for interoperability.

Given the uncertainty surrounding certification, the AHA urges CMS to adopt a single exception without the certification requirement, not two exceptions for the pre- and post-interoperability

periods. CMS and the HHS Office of Inspector General (OIG) could revisit the exception at a later date to require compliance with interoperability standards once they have been agreed upon. This would allow the standards to be developed, tested and implemented, and give CMS and the OIG the opportunity to review the arrangements that have been made in the interim. It also would also put vendors on notice that progress toward interoperability is essential. This single exception would need to broaden the scope of covered technology and address other specific concerns noted in the comments below.

Breadth of regulatory authority

CMS has used general authority under section 1877(b)(4) of the Social Security Act to propose the EHR-related Stark exceptions. This section specifically exempts from the Stark law's prohibition on certain physician referrals "any other financial relationship that the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse." This section, therefore, clearly anticipates the Secretary's determination that a broad array of financial relationships do not risk the kind of abuses the Stark law was designed to deter, and gives the Secretary wide latitude to identify and describe them through regulation. The AHA is concerned that CMS has not exercised fully this broad congressional mandate and has proposed EHR-related Stark exceptions that are unnecessarily restrictive, especially in the "pre-interoperable" phase.

CMS indicates that their proposed exceptions are concerned with the risk of program abuse "that *may* be posed" [emphasis added] by the provision of valuable technology to physicians, pointing out that the provision of EHR technology poses a greater risk of abuse because it is "inherently more valuable to physicians in terms of actual costs, avoided overhead, and administrative expenses of an office practice." CMS, however, does not specifically identify any negative impacts resulting from the provision of EHR technology. Rather, CMS describes a significant number of benefits to patient care and quality anticipated from the adoption and use of such technology, including allowing patient information to move with consumers from one point of care to another, permitting clinician access to critical health information as treatment decisions are being made, and reducing medical errors. As CMS acknowledges, these benefits are consistent with national priorities for improving the health care system and CMS' own goals in exploring pay-for-performance options. The AHA urges CMS to discard the narrow view used in constructing the proposed EHR-related Stark exceptions and offer a broad exception consistent with the mandate of section 1877(b)(4). As CMS explains in the preamble to the proposed exceptions, it can continue to evaluate the risks posed by the donation of electronic health records technology to physicians and refine or add appropriate safeguards to the exception as the ongoing evaluation necessitates.

E-prescribing exception

Specifically, the proposed rules provide an exception for stand-alone e-prescribing systems. While the AHA understands that the Medicare Modernization Act of 2003 (MMA) directed CMS to develop an exception specifically for e-prescribing, hospitals are not likely to take advantage of an e-prescribing-only exception to the Stark laws because it is too narrow.

Hospitals and physicians need to exchange clinical information across the spectrum of care, including ambulatory, inpatient, post-acute and long-term care. For the greatest impact on quality and patient safety, e-prescribing should be an integrated piece of the full EHR, so that patients' diagnoses, allergies and treatments are accessible and known when prescriptions are made. In addition to being too narrow, the proposed rules provide an exception for stand-alone e-prescribing systems that are generally not found in the market.

Pre-interoperability EHR exception

The AHA has concerns with several elements of the proposed regulations contained in the pre-interoperability section, most of which will apply to all three of the proposed exceptions.

Defining "necessary"

The MMA limited the exception to "necessary" items or services, but we believe CMS has defined "necessary" too narrowly. Expressing concerns about increased risks of recipients intentionally divesting themselves of technology items or services they already have, CMS states explicitly that the exception would not cover the provision of items or services that are "technically or functionally equivalent" to those the recipient currently poses or has obtained. CMS, however, indicates that it does not interpret "necessary" to preclude upgrades that significantly enhance the functionality of the item or service. CMS offers no further guidance on the meaning of "technically or functionally equivalent" or what is meant by "significantly enhance the functionality" of the item or service. Rather the recipient would be required to "certify" that items and services to be donated are not equivalent. Additionally, the donor must not have actual knowledge of, and act in reckless disregard or deliberate ignorance of, the fact that the recipient possesses or has obtained such equivalent items or services.

Recipients are unlikely to possess the sophisticated level of understanding of capabilities and functionalities of available technology items and services that this standard seems to require. The burden and expense of making such determinations, therefore, is likely to fall primarily on hospitals and others who are donating the technology. Without clearer guidance on the terms used in the regulation and precisely how to make equivalency determinations, hospitals will not have confidence in the proposed exception. For example, if a physician already has a hand-held device that would be sufficient to run the requisite EHR software, but would require extensive and costly modifications to enable it to communicate with the hospital's existing information system, would a replacement be characterized as "technically or functionally equivalent?" CMS should offer guidance that enables any physician to make the required equivalency determination without needing to engage expensive technical and legal consultation services. In addition, CMS should facilitate sharing technical information about equivalency across donors and recipients so that they can take advantage of existing information and avoid duplicative efforts.

Covered technology

The proposed rule narrowly defines the covered technology as EHR software that does not include administrative functions but does include e-prescribing modules that conform to

Medicare Part D standards just published. Directly-related training is the only permitted support under the proposed rule.

The AHA is concerned with the narrow definition of covered technology. The products on the market increasingly integrate administrative functions with the clinical EHR. From the physicians' point of view, greater efficiencies and clinical benefits will be gained when these functions work together seamlessly. Many situations require merging administrative and clinical data: clinical data must be accessed to support automatic prescription refill authority, clinical data must be aggregated for quality reporting, bills are derived from the clinical record, etc.

Furthermore, while software and directly-related training clearly are important to physician adoption of EHR, they are not sufficient. Physicians may not have the technical knowledge or resources to procure, implement and manage all of the necessary items. In addition, as hospitals expand their IT systems, they must incorporate communication and data transfer capability to physician offices into their IT infrastructures. In a wired health care system, physician access to hospital IT systems and communication between hospitals and physicians will be as necessary to providing high quality care as use of an operating room and recovery suite. Hospitals will need to maintain this IT infrastructure and protect its security and integrity. For these reasons, hospitals may want to provide other kinds of support to physicians to ensure that implementations are successful and information can be exchanged safely, such as:

- T1 lines or other enhanced broadband connectivity, including those needed to support transfer of medical images and EKGs, particularly in rural areas. This may include related software and hardware, such as routers to speed download times.
- Secure connections and messaging. Without ensuring that physician office systems have adequate security protocols and secure messaging, hospitals could put their own IT systems at risk when they connect.
- Ongoing maintenance and support. If physician office systems are not upgraded and maintained in the same manner as hospital systems, the ability to share clinical data to improve care will not be sustained.
- Interfaces. If a physician office already has an EHR that is not easily interoperable with the hospital system, the hospital may wish to provide the programming and software needed to interface the two systems. This kind of support clearly promotes interoperability, but is not allowed under the proposed exception.

Given the nature of technology, many of these items are multifunctional. For example, physicians could use the connectivity that allows them to exchange data with the hospital to also access general internet sites. However, it is not practical, and does not promote interoperability, if physician offices must use a connection only to exchange data with a given hospital. We urge CMS to define multifunctional connectivity, including related software and hardware, as covered technology. Incremental approaches may be possible, where the technology necessary for connectivity is covered, while any costs associated with additional uses are borne by the physician.

While existing fair market value exceptions, which allow hospitals to sell IT items and services to physicians at the prevailing market rate, could be used for these kinds of arrangements, it is difficult, burdensome and costly for hospitals to make these calculations, particularly when the costs incurred by the hospital often are lower than the market costs due to economies of scale. Lack of technical knowledge and resources may limit physicians' willingness to pursue fair market value arrangements. Difficulties in determining fair market value have prevented hospitals from establishing arrangements with physicians in the absence of a specific IT exception. Given the severity of the penalties, clear guidance is needed.

Standards

The AHA urges that CMS not require that permitted support conform to the BioSense (Public Health Information Preparedness) standards. BioSense is a national program to advance a new type of biosurveillance at the national, state and local levels, and includes certain public health information reporting standards. These standards have not been widely discussed or adopted industry-wide. More research is needed on their appropriateness for the private sector and readiness for implementation. In addition, requiring compliance with these standards while the broader standardization and certification efforts are underway could prove counterproductive.

Permissible donors and selection of recipients

Permissible donors are those in the protected arrangement between a hospital and physicians who are members of the medical staff that routinely furnish services at the hospital. However, the growth of hospitalists and intensivists means that many physicians are admitting patients to the hospital, but not furnishing services in the hospital. In these cases, the need for clinical information exchange is even greater, since the hospital-based physician in charge of the patient will not have the same knowledge as the admitting physician. Similarly, many physicians refer patients to hospitals for outpatient care, and would benefit from having electronic access to test results that they can incorporate into their own EHRs. Therefore, the AHA urges CMS to change the criteria to physicians on the medical staff whose patients frequently receive inpatient and outpatient care at the hospital.

While allowing hospitals to donate covered technology to members of the medical staff, the proposed rule states that IT cannot be used to entice physicians away from other hospitals. While the AHA understands the pro-competitive intent of this restriction, it puts hospitals in a difficult spot. Will offering covered technology to all members of the medical staff – including new members – be construed as an attempt to entice physicians away from other hospitals? If so, how can they ensure all physicians are connected? The AHA urges CMS to drop this provision to allow hospitals to work with new members of their medical staff, without being seen as trying to entice physicians from other hospitals.

The proposed rule states that physician selection criteria may be allowed in the post-interoperability period. We infer from the lack of reference to selection criteria in the pre-interoperability period that this would not be allowed. However, as a practical matter, if they are

to help physicians adopt EHRs, hospitals will need to choose which physicians they work with at the beginning of the exception, and how they roll out their donations.

The AHA urges CMS to allow selection criteria and protect specific criteria that make operational sense, even if they could be construed as related to volume and value of referrals, as long as those criteria are linked to achieving greater improvements in quality of patient care or greater likelihood of success in increasing physician adoption of IT. The kinds of criteria that hospitals might want to use, and which would need protection, include:

- Participation in hospital quality improvement activities;
- Participation in medical staff meetings and activities;
- Specialty (the need to exchange data is often greatest for internal medicine or general practice);
- Department (IT systems are often rolled out by department);
- Readiness to use health IT;
- Consistent use of hospital-based IT systems, such as order-entry functions;
- Acting as a physician champion of hospital-based IT systems;
- Willingness to serve as a trainer for other physicians;
- Size of medical practice (it can be more efficient and effective to work with larger practices, which are often more ready to adopt IT); or
- Willingness to contribute some resources to the IT project

The AHA is concerned about how CMS and the OIG will determine whether or not IT donations are related to volume or value of referrals, as enforcement is not discussed in the proposed rule. We anticipate that the act of increasing information exchange between hospitals and physicians will lead to greater quality of care in the hospital. Consequently, physicians may increase their use of hospitals that provide this better quality of care – a good outcome for the patient and payers. However, an ex-post-examination of admitting patterns could conclude that the donation was related to volume or value of referrals.

Cap on value

CMS suggests that it would be "appropriate to limit the aggregate value" of the technology a donor could provide to a recipient under the exception, believing that such a limit would minimize the potential for fraud and abuse. The AHA believes that current imposition of any cap on the value of donated technology is, at best, premature and may unnecessarily and inappropriately inhibit wide-spread adoption. Hospitals' available financial resources necessarily will limit their ability to donate technology and related services to physicians and we are unlikely to see an explosion of hospital purchases of expensive and unnecessary technology as a result of the creation of an EHR-related Stark exception. Hospitals' choices to extend technology to their physicians are likely to be dictated by careful consideration of specific needs in light of clearly defined goals and objectives for the sharing of clinical information and improvements in quality of care. In an initial period where the goal is to encourage greater technology adoption, the appropriate level for a cap on the value of any donations to specific

physicians can be determined accurately only by considering needs and understanding associated benefits and costs of the use of specific technology.

As the adoption of technology becomes more widespread, CMS can monitor these developments and reconsider the appropriateness of imposing a cap on value, based on a better and more sophisticated understanding of technology costs and the impact on improved information exchange and enhanced quality of patient care. The imposition of a cap must give careful consideration to the complexity of how value is determined, if the requirement is to avoid unnecessarily burdening donors with the need to obtain costly valuation consultation services and analyses. If CMS' review suggests the need to impose a cap at some later time, the AHA urges the agency to base the cap on hospitals' actual costs rather than fair market value to the recipient. Hospitals likely will receive significant discounts due to volume purchases and other economies of scale and have a better understanding of their own costs. They would require costly and time-consuming outside valuation services and analyses to determine fair market to the recipients.

Other conditions

The AHA applauds CMS for including the condition that physicians cannot make receipt of technology a condition of doing business with a hospital. Not all hospitals are in a position to assist physicians in adopting EHRs, and they should not be coerced into doing so.

The proposed rule also requires that covered arrangements not violate the anti-kickback law. Given this condition, the impact of any exception to the Stark regulations on physician use of IT will be minimal if there is not a parallel safe harbor to the anti-kickback regulations. While the anti-kickback statute requires intent of wrong-doing, and is therefore more difficult to violate, the severity of the criminal penalties limit hospitals' willingness to act without specific guidance. The AHA is also submitting comments to the OIG on their proposed rule.

Post-interoperability exception

As noted already, the AHA urges CMS to provide for a single exception, rather than introducing both pre- and post-interoperability exceptions. However, if CMS chooses to follow this path, it must finalize the post-interoperability rules at the same time as the pre-interoperability rules. Without clear guidance on what to expect in the post-interoperability period, hospitals will not be able to make informed plans. In the proposed rules, CMS states its intention to wait until the Secretary has adopted certification criteria to finalize the post-interoperability regulations. This action will delay urgently needed support for physician adoption of EHRs.

In addition, certification requirements in the post-interoperability period must accept CCHIT criteria as sufficient for the purpose of the exception even if CCHIT has limited criteria for interoperability. While the proposed rule mentions CCHIT, it does not clearly state that only one certification process will be used. It would be confusing and burdensome if the Secretary established a separate certification mechanism for the purposes of the Stark exception.

The AHA strongly urges CMS to rethink the approach adopted in this proposed rule. A single exception that addresses our concerns will go far toward achieving the policy goal of increasing physician use of IT and expanding information exchange. Without these changes, hospitals will not have the flexibility they need to work constructively with physicians to realize the promise of IT for improving quality of care.

The AHA stands ready to provide any assistance to remedy the concerns outlined. Questions about our comments can be directed to me, Chantal Worzala, senior associate director of policy, at (202) 626-2319 or cworzala@aha.org, or Lawrence Hughes, regulatory counsel and director, member relations, at (202) 626-2346 or lhughes@aha.org.

Sincerely,

Rick Pollack
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PARTNERS

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December 9, 2005

VIA FEDERAL EXPRESS

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Re: Comments to Proposed Stark Law Exception and Anti-Kickback Statute Safe Harbors For Certain Electronic Prescribing and Health Records Arrangements

Dear Dr. McClellan and Mr. Levinson:

This letter is submitted on behalf of Partners HealthCare System, Inc. ("Partners") to comment on the Notice of Proposed Rulemaking for Stark Law "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions For Certain Electronic Prescribing and Electronic Health Records Arrangements" (the "NPRM"), 70 Fed. Reg. 59181 (October 11, 2005), and the parallel proposed rule to create additional safe harbors under the Anti-Kickback Statute, 70 Fed. Reg. 59015 (October 11, 2005). Although the specific focus of our comments will be the Stark Law NPRM in section B below, we provide brief comments in section C on the Anti-Kickback Statute safe harbor. Because the reasons for the standards and criteria for a Stark Law exception for provider-supported electronic health records ("EHR") are similar for an Anti-Kickback Statute safe harbor, we submit our comments about the NPRM to the Office of Inspector General as well for its consideration under its rulemaking.

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At the outset, we want to express our appreciation to CMS for its commitment to furthering the national policy of encouraging the development of EHR technology, and for the obvious time and energy CMS staff spent in developing the proposed rule. We also want to recognize the efforts CMS and staff made in conducting this effort through the open process it employed in this rulemaking. Partners remains committed to working with CMS and OIG to develop workable final rules that encourage EHR support within the statutory fraud and abuse framework within which we must operate.

A. BACKGROUND OF PARTNERS AND ITS SIGNATURE INITIATIVE TO EXPAND USE OF ELECTRONIC HEALTH RECORDS ACROSS ITS PHYSICIAN NETWORK

Partners is one of the largest charitable diversified health care services organizations in the United States. It was founded in 1994 by Brigham and Women's Hospital and Massachusetts General Hospital in order to create an integrated delivery system ("IDS"). In addition to the founding academic medical center ("AMC") hospitals, the Partners IDS now includes three community acute care hospitals that are owned by Partners, three community acute care hospitals that participate in Partners' managed care contracting, one hospital providing inpatient and outpatient mental health services, three hospitals providing inpatient and outpatient services in rehabilitation medicine, and a physician network of approximately 5,900 primary care physicians (PCPs) and specialists. Partners' physician network is operated through Partners Community HealthCare, Inc. (PCHI), which is a management services organization formed to support the implementation of an integrated managed care strategy.

To help focus the organization on strategic goals, Partners has developed five Signature Initiatives that are intended to move Partners much closer to a truly integrated health care delivery system that improves the quality, safety and efficiency of care for its patients. The Signature Initiatives are: 1) maximizing the use of new clinical information technology; 2) increasing patient safety and reducing medical errors; 3) making high quality patient care uniform across the Partners system; 4) coordinating care for patients with high cost diseases; and 5) improving the efficient use of prescription drugs and radiology procedures. The back-bone of these Signature Initiatives is EHR because it is physicians' use of EHR technology that will drive the success of the other Signature Initiatives. To date, programs instituted under the Signature Initiatives have improved the quality of care for the sickest patients by meeting or exceeding national standards for the treatment of heart disease and diabetes; have reduced hospital re-admissions for patients with congestive heart failure by 20 percent in a large pilot and have improved coordination of care for these high-cost patients; and have reduced the rate of increase in outpatient drug costs.

As a further means for implementing the Signature Initiatives and achieving its goals of improving the efficiency and quality of patient care, Partners has adopted a

"pay for performance" managed care contracting model in which significant portions of the network providers' compensation are contingent upon their achieving improvements in defined efficiency and quality of care targets rather than being measured against fully inclusive medical budgets. The contracts Partners has in effect with the major HMOs in Massachusetts all contain some form of such pay-for-performance incentives, covering approximately 529,000 lives as of March 31, 2005. Under these contracts, specific quality and cost-effectiveness performance measures are established separately for the Partners IDS hospitals and physicians. One of the performance measures is the adoption of a common EHR system throughout by the Partners IDS network physicians.

Currently, while 83 percent of Partners' AMC physicians are using electronic medical records, the level of participation by its community-based network physicians lags behind. To accomplish the goals of the Signature Initiatives and to reach its pay-for-performance contract targets, Partners has determined that it is necessary to provide financial support to its community network physicians to assist them in deploying EHR technology.

Of note, Partners estimates that of its community network physicians targeted for EHR support, approximately 63 percent have primary affiliation relationships with hospitals that are not owned by Partners (71 percent for primary care physicians). Partners is committed to the goal of delivering high quality medical care in community settings, and therefore its care delivery model is based on maintaining the relationships that its community-based network physicians have with their community hospitals. Consequently, Partners does not intend -- nor anticipate -- that its community network physicians will shift referral patterns as a result of Partners' support for EHR adoption.

Partners has developed its own proprietary ambulatory-care electronic medical record system known as the Longitudinal Medical Record or "LMR" which is used by Partners physicians and other clinical staff in the outpatient setting.. The LMR has a broad set of features to support the documentation and delivery of care including:

- The ability to capture and store health information including medications, problems, allergies, health maintenance events, lab results, and visit/encounter notes;
- E-prescribing with embedded drug-to-drug and drug-allergy checking;
- Tools to facilitate the management and communication of lab results;
- Reminders, alerts, templates and other forms of clinical decision support to improve the quality, safety and efficacy of care;
- Clinical messaging to support communication within the care team;
- Interfaces to patient administrative systems;
- Reports and other population-based views of patient information; and
- A patient portal to facilitate patient communication and information exchange.

c. Recommendations

As discussed above, we urge CMS to permit the same covered technology during the pre- and post-certification period.

CMS should clarify the components of acceptable EHR software. Specifically, CMS should permit the following:

- Software interfaces.
- Upgrades to the initial software. This clarification will help alleviate some of the wait-and-see concerns discussed above. We can foresee that an initial vendor's product may not meet the certification standards that are adopted and revisions will need to be made. Obviously, it makes sense that financial support for such upgrades be permitted.
- Ongoing technical maintenance and support for software. Almost universally, vendors provide software maintenance and support either as a bundled component of initial software license/purchase price or as a fee-based add-on. We urge CMS to make clear that such support is equally protected as the software itself.

In addition, to the extent that CMS determines that additional items and services need to meet a fair market value standard, we urge CMS not to require providers to develop complicated methodologies to determine fair market value, nor should they be required to engage outside valuation experts. Rather, CMS should make clear that it will instruct Medicare fiscal intermediaries to accept any reasonable, objective methodology, including approximations, that is maintained in a written record.

3. COMPLIANCE STANDARDS

All of our comments on compliance standards have been made above in section B.1.b.

4. PERMISSIBLE DONORS

a. Relevant NPRM Provision

The NPRM tracks the MMA e-prescribing authority for the list of permissible donors. Hospitals are included on the list. However, the NPRM does not expressly protect and therefore appears to exclude other organizations that are affiliated with hospitals, such as IDSs and their component organizations including network providers (such as affiliated physician groups), physician hospital organizations, management service organizations and IDS parent companies, such as Partners.

b. Comments

We urge CMS to make clear that permissible donors include the various components of hospital-based IDS systems. We see no rational basis for excluding IDSs, and assume the NPRM did not include such hospital networks only because they were not listed in the MMA e-prescribing authority's list of permissible donors.

c. Recommendations

Permissible donors should include any component of an Integrated Delivery System. For the purposes of this exception, we recommend the following definitions:

> "Integrated Delivery System" or "IDS" means a system of provider organizations that includes, at a minimum, a parent entity that owns or controls one or more hospitals, and one or more of the following components:
>
> i. Network Providers,
> ii. An entity that operates, supports or manages the Network Providers,
> iii. A physician-hospital organization or physician organization.[3/]
>
> "control" means, with respect to two non-profit entities, "A" and "B":
>
> i. A's status as sole member of B,
> ii. A's power to appoint or control a majority of B's Board of Directors;
> iii. Reserve powers in B, held by A, that trigger either (i) or (ii) above based on specified events.
> iv. Other similar powers recognized by state law.
>
> "Network Providers" means any combination of two or more providers or suppliers, such as Physicians, Group Practices or Hospitals, that either (i) are owned, controlled or managed by a component of an IDS; or (ii) participate with one or more components of an IDS in managed care contracting, such as pay-for-performance contracting.

3/ In identifying these entities as components of an IDS, we do not wish to imply that we object to such entities operating as stand-alone organizations qualifying as permissible donors.

5. SELECTION OF RECIPIENTS

a. Relevant NPRM Provision

Although there are other permissible recipients in the NPRM, the category of concern is the limitation to physicians who are on the medical staff of the donor hospital. (Subsections (w)(1)(i) and (x)(1)(i)) This category is derived from the MMA e-prescribing authority.

In addition, as discussed in section B.1.a above, the NPRM makes a distinction in the two exceptions between not taking into account referrals and not directly taking into account referrals or business generated, the latter standard being easier to meet. Moreover, the post-certification exception (subsection (x)(4)) articulates six approaches hospitals and other providers could adopt to select physicians eligible to receive EHR that would be deemed not to directly take into account referrals or business generated. Two of these approaches state that the determination may be based "on the total number of prescriptions written by the recipient;" or "the size of the recipient's medical practice (for example, total patients, total patient encounters, or relative value units)." Subsection (x)(4)(i) and (ii). The pre-certification exception contains no similar language, nor is there language that would specifically prohibit the six deemed approaches.

b. Comments

i. Inclusion of Network Physicians

Physicians participate in the Partners IDS network to achieve shared quality and efficiency improvement goals which are promoted through clinical integration. The adoption of interoperable EHR systems throughout the Partners network will be a significant factor in the network's ability to achieve these goals. Accordingly, as discussed in section A above, Partners' managed care contracts with the significant Massachusetts HMOs include network-wide physician adoption of EHR technology as one of the pay-for-performance measures. Moreover, the adoption of network-wide interoperable EHR systems will reduce the network's dependence on payer-generated utilization and quality data and will enable the Partners network providers to expand their quality and efficiency improvement programs to broader patient populations, including Medicare and Medicaid patients. Of the non-AMC Partners network physicians whom Partners has targeted for EHR support, approximately 63 percent have primary affiliation relationships with community hospitals not owned by Partners. Under the NPRM, these physicians would not be eligible for EHR support from Partners or any of its hospitals, and thus the additional funding from payors through pay-for-performance incentive payments and the opportunity to expand the reach of the network's quality and efficiency improvement programs may be lost as a result.

We see no basis for restricting permitted recipients to physicians on the medical staff of the donor hospital. We believe that the other proposed fraud and abuse restrictions in the NPRM make it sufficiently clear that EHR support cannot have a referral based-premise. Specifically, we understand the concern that remuneration not be used to induce physicians who already practice at other hospitals to join the medical staff of a different hospital. However, we think such a practice is clearly prohibited under proposed subsections (w)(3) and (x)(3), which require that the donated support not be used as a condition for doing business with the hospital.

Moreover, the expansion of permissible recipients to include physicians who are not on the medical staff of the donor hospital will promote CMS's goals of interoperability. The reason is that these physicians, by definition, have their primary hospital affiliation with another hospital, and consequently they will want the donor's EHR system to be interoperable with the system that is developed at their primary hospital.

ii. Eligibility Standards[4/]

The NPRM is unclear whether any selection criteria are permitted in the pre-certification exception. If it was CMS's intent during the pre-certification period to preclude the selection criteria specifically allowed in the post-certification rule, we submit there is no rational basis for this restriction.

Part of the problem stems from the distinction in the pre-certification exception that physician eligibility not take into account referrals or business generated and the post-certification statement that such eligibility not directly take into account referrals or business generated. We submit that this is a distinction without a difference in the real world, and is not a sufficient basis for precluding the selection criteria during the pre-certification period.

c. Recommendations

i. Inclusion of Network Physicians

CMS should expand the group of eligible recipients to include Physicians and Group Practices that are Network Providers as we have defined that term in section B.4.c above.

4/ Our comments on the eligibility standards also pertain to the criteria for the amount and nature of support.

We also urge CMS to expand permissible recipients to include NPs, PAs and other independent, licensed practitioners to the extent that any of these practitioners are defined under Medicare law to constitute a "physician" and therefore subject to the Stark law.[5/]

ii. Eligibility Standards

Regarding the eligibility standards contained in subsections (w)(4) and (x)(4), we urge that the distinctions be eliminated, specifically, that the six deeming rules should apply to EHR support given prior to the adoption of interoperability standards. At a minimum, we urge CMS to make clear that an acceptable eligibility standard is the size of a physician's practice.

6. VALUE OF PROTECTED TECHNOLOGY

a. Relevant NPRM Provision

CMS at various times in the preamble expresses a concern about the relatively high value of the protected technology and specifically solicited comments on whether it should impose a cap on the value of the protected technology, and whether hardware, connectivity and related items and services should be protected. 70 Fed. Reg. at 59187-188.

b. Comments

We believe that a cap on the amount of permitted support will potentially raise significant problems and will not provide any meaningful protection against patient or program abuse. We note that CMS seems to assume that EHR adoption will entail a large up-front expense, which is not necessarily the case (and is not the case under the current Partners pricing model for its LMR system, which contemplates an annual bundled license and maintenance fee). There are significant practical difficulties in determining the value of the donated technology to the recipients, most importantly the value (on a per-physician basis) is largely determined based on the size of the practice, and therefore the cap could be triggered for small practices, but not larger ones.

c. Recommendations

We recommend that no cap be imposed on the amount of permitted support. However, to the extent CMS believes it necessary to provide a cap, we urge such a cap be sufficiently flexible to accommodate both up-front purchase and annual subscription or licensing fee pricing models, and should permit the provision of financial support over a number of years, subject to a lifetime maximum. Providers should be allowed to

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5/ We understand that the OIG's authority is not limited to physicians as defined by Medicare.

use alternative methodologies in which to calculate the cap. One approach we recommend is to permit the support to cover up to three-quarters of the total the cost of the EHR package. Further, we urge that the calculation of the cap be based on the cost of the EHR system to the donor rather than on the value to the respective recipient practices. Regarding our recommendations for the calculation of the fair market value of the permitted support, please refer to our recommendations in section B.2.c in which we recommend that CMS not require providers to develop complicated methodologies, nor require the use of outside valuation experts. Additionally, we recommended that CMS should instruct its Medicare fiscal intermediaries to accept any reasonable, objective methodology, including approximations, that is maintained in a written record.

7. OTHER

We urge CMS to use its existing case-by-case advisory opinion authority to set forth areas where it will consider additional standards and criteria.[6/] CMS used this approach in considering community need in the physician recruitment exception. This approach, if applied selectively, would give CMS the discretion to analyze individualized circumstances that may not otherwise be permitted in a broader rule. We gave one example above of permitting an extended grandfathering period for non-certified EHR systems.

C. COMMENTS ON ANTI-KICKBACK SAFE HARBOR PROPOSED RULE

We urge the OIG to provide a safe harbor whose only requirement is compliance with the parallel Stark Law exception.[7/] We submit that any regulation CMS adopts under its authority of section 1877(b)(4) should provide sufficient protection under the Anti-Kickback statute. In addition, because the OIG did not propose specific regulatory text language, we urge the OIG to promulgate a rule with an additional comment period.

* * * * *

Partners is a member of the American Hospital Association, the Association of American Medical Colleges, and the National Alliance for Health Information Technology, and we concur with their comment letters to the extent not inconsistent with this letter.

6/ See Crane letter dated August 30, 2005, regarding CMS's case-by-case advisory opinion authority.

7/ We think there is a larger issue CMS and the OIG need to tackle regarding the interplay between Stark exceptions and OIG safe harbors. In particular we believe that CMS has the staff capability to craft exceptions that meet the statutory requirements under (b)(4) without needing to impose the requirement of Anti-Kickback statute compliance. We think this requirement imposes ambiguity and reverses the more logical equation that Stark Law compliance should be sufficient for Anti-Kickback statute safe harbor protection.

In closing, we appreciate this opportunity to comment on this important policy initiative. Please do not hesitate to contact either of us if we can be of further assistance.

Respectfully submitted,

Brent L. Henry
Vice President and General Counsel

Thomas S. Crane
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
Counsel to Partners HealthCare System, Inc.

LIT 1549835v.11

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DEC 12 2005

December 8, 2005

Via Overnight Delivery
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1303-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Enclosed please find an original and three copies of Bluegate Corporations comments to File Code CMS-1303-P. Please retain the original and two copies for your records and return to us one file stamped copy in the enclosed self-addressed envelope.

Thank you,

William E. Koehler,
President and Chief Operating Officer

cc: Greg A. Cardenas
Byrne, Mead & Smitherman
5400 LBJ Freeway, Ste. 1325
Dallas, TX 75240

701 North Post Oak Road, Suite 630 • Houston, Texas 77024
713 686-1100 • 713 682-7402 fax

December 8, 2005

Via Overnight Delivery
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1303-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1303-P: Comments to Proposed Rule Creating New Stark Law Exceptions

Bluegate Corporation ("**Bluegate**") provides HIPAA-compliant, interoperable, medical grade telecommunications networks, healthcare information technology services, and managed security solutions to hospitals, physicians, and Regional Healthcare Information Organizations. Bluegate makes possible secure, interoperable, and HIPAA-compliant electronic data creation, retention, and communication by and among hospitals, medical facilities and physicians. A seamless, interoperable, and HIPAA compliant electronic data communication network will enhance patient care and reduce the cost of healthcare while safeguarding the privacy rights of patients. Improving patient care, increasing efficiency, reducing cost, and protecting individual privacy should be the hallmarks of any government endorsed healthcare information network.

In furtherance of these goals, Bluegate submits the following comments to File Code CMS-1303-P, *Medicare Program: Physicians' Referrals to Health Care With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements* (the "**Proposed Rule**"). Section I below provides background information supporting Bluegate's contention that the Proposed Rule should be revised to ensure that certain specific items and services are included as Covered Technology under the Proposed Rule. Section II below includes specific comments to specific subsections of the Proposed Rule.

I. INTRODUCTION

The "Last Mile" is the figurative distance from a telecommunication provider's switch to a residential customer. Bridging the Last Mile involves assessing existing information technology infrastructure, and providing the needed physical infrastructure, connectivity, hardware, software, and support services to bring high-bandwidth applications to the customer. For a residential customer, high bandwidth applications include on-demand television, fast internet access, and web pages full of multimedia effects. The overall expense of bridging the Last Mile for a single telecommunications customer often makes it cost-prohibitive. The telecommunications industry continues to struggle with how to economically bridge the Last Mile and deliver high bandwidth to individual homes across the country.

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What is envisioned in healthcare is a National Healthcare Information Network ("**NHIN**"), a complex network infrastructure operating over a secure broadband network that will connect physicians with healthcare providers, enterprise information systems and other healthcare stakeholders. The goal of the NHIN is to deliver to the healthcare industry high-bandwidth applications that include electronic drug prescribing, as well as the efficient and HIPAA compliant storage, transmittal, receipt, viewing and manipulation of electronic health records and images. The Last Mile of the NHIN is the figurative distance from a telecommunication provider's switch to an individual physician's office (the "**Last Healthcare Mile**"). The same issues that create challenges in economically bridging the Last Mile for residential users also apply to the NHIN, but healthcare industry applications also place several additional demands on a network infrastructure that are even more costly and challenging to healthcare providers and customers.

First, many healthcare applications such as imaging and telemedicine require immense amounts of bandwidth. Second, this data is optimally routed over a high speed network that federal law requires be HIPAA compliant. Third, because medical records created and stored at one physician office must be seamlessly transmitted and received by other healthcare providers and facilities, this network must be interoperable. Thus, bridging the Last Healthcare Mile requires comprehensive systems management which will not only provide appropriate bandwidth, but will also ensure a high speed, HIPAA compliant network connection that is interoperable.

To achieve this, the NHIN must be fully supported both technologically and practically. This means (i) assessing a physician's current technology to determine what is needed to supplement existing IT equipment and resources to fully support an interoperable network, (ii) providing appropriate internet connectivity to obtain needed bandwidth, (iii) providing appropriate hardware and software to carry and utilize that bandwidth to and within a physician office, (iv) providing appropriate security to ensure HIPAA compliant privacy protection, and (v) providing appropriate monitoring, training, and ongoing technical support to ensure continued security and network viability. Critical healthcare data will be transported over the NHIN, thus mandating a high degree of uptime and availability.

Unfortunately, the typical end user of the NHIN (i.e. the physician) lacks the relevant technical expertise to be responsible for supporting his or her end point connection. The personnel responsible for establishing and maintaining this sophisticated network on behalf of a single physician office or group practice typically has little or no professional information technology support for their own information technology infrastructure. Further, they are not capable of configuring, implementing and maintaining an interoperable information network intended to seamlessly communicate and share information with other similarly situated, resource constrained, providers in a HIPAA compliant fashion. The NHIN is literally the conduit for access to and the exchange of all electronic health information. Without a secure, HIPAA compliant NHIN, electronic drug prescribing and electronic health record systems on any meaningful scale is simply impossible.

Bluegate believes that the benefits of the NHIN will never be realized unless an appropriate infrastructure exists to deliver these applications to health care professionals. Intersecting the practical technological challenge described above is the question of who will pay for building the NHIN. At present, the success of the entire NHIN depends on physicians themselves to optimally, securely, and interoperably connect to and from the NHIN, with no standard requirements. Physicians lack the technical expertise, financial resources, and individual incentive to accomplish this feat. History has confirmed that if the information system in healthcare is unreliable or difficult to use, it will be rejected by physicians and will fail instead of being embraced and flourishing.

Physicians as a group are generally viewed as the greatest source of valid clinical health data, as well as the group that must commit to the NHIN for it to be successful. Today, this group bears the full financial burden of employing information technology in their practices, without the ability to receive any legitimate help on connecting to the NHIN from the enterprises that would most benefit from their group's participation. With only a few narrow and ambiguous exceptions, current regulations permit only physicians to pay for their own network connectivity, security and network support. Third parties have expressed an interest in assisting physician offices in making the necessary investment in building and supporting a comprehensive, robust, interoperable, HIPAA compliant NHIN. There are understandably regulatory limitations on who can make such an investment on behalf of a physician. Nevertheless, these regulations pose a major obstacle to the development of a sophisticated and complex NHIN, because the weakest point of the network, the Last Healthcare Mile, is the one that is most critical to its success.

Maintaining existing policy leaves in place a technologically flawed and financially limited plan to develop an interoperable, efficient, reliable, and secure NHIN. As a result, the healthcare industry will continue to resist information technology, or will administer it poorly, resulting in certain failure for the NHIN in the time frame envisioned by the current administration. The NHIN is the backbone of all electronic healthcare communications. Bluegate believes that government policy and regulation should alleviate physicians of some of the financial burden associated with developing a comprehensive NHIN and permit that burden to be borne by the entire healthcare infrastructure that ultimately benefits from the physicians being connected in an efficient and properly regulated NHIN. A critical element of this policy is the ability of permitted donors to make investment in all items and services necessary to develop and maintain a robust, secure, and reliable NHIN.

Specifically, the Proposed Rule should permit the provision by qualified donors of non-monetary remuneration that includes (i) broadband internet connectivity, (ii) network infrastructure, including hardware and software, (iii) network security, including firewalls, anti-virus software, hardware protection, (iv) HIPAA compliant security and monitoring, and (v) training and systems monitoring. The proposed exceptions do not provide potential donors with sufficient comfort that these items and services may be provided to qualified recipients. Bluegate believes these items are either currently intended to be permitted items or services, or are logical and necessary additions to the list of permitted items and services.

Given that electronic prescribing and electronic health record systems require a NHIN in order to ensure that data transmittal, receipt, and access are facilitated in a secure, interoperable, and compliant manner, Bluegate would further submit that the provision of other non-monetary items (such as hardware, software, etc.) to a physician that is not connected to a secure, interoperable and compliant network does not in and of itself enable the recipient to utilize an

electronic prescribing or electronic health records network. For that reason, Bluegate believes the provision of any items and services to a physician should be predicated on that physician having access to a secure, interoperable, compliant network that can utilize the provided items and services to engage in compliant electronic communications and commerce.

The expense of these products and services is relatively low, but they would serve a vital and practical function. Clarity that the donation of these items is permitted will encourage investment from qualified donors, who will directly benefit from being able to better communicate with physicians over an interoperable information platform. This investment will accelerate the implementation of a comprehensive, interoperable, secure NHIN.

Commercial markets like certainty. If the final rule explicitly includes these items and services as permitted non-monetary compensation, Bluegate is confident that qualified donors and physicians will work together to bridge the Last Healthcare Mile and complete a comprehensive, interoperable, efficient, and secure NHIN.

II. COMMENTS TO PROPOSED RULE

A. Electronic Prescribing Exception; §411.357(b)

1. "Necessary" Non-Monetary Remuneration

The Proposed Rule would protect "Non-Monetary Remuneration (consisting of items and services in the form of hardware, software, or information technology and training services) necessary to receive and transmit electronic prescription information," subject to certain conditions. Bluegate believes that permitted non-monetary remuneration must specifically include the following items and services: (i) broadband internet connectivity, (ii) network infrastructure, including hardware and software, (iii) network security, including firewalls, anti-virus software, and hardware protection, (iv) HIPAA compliant security and monitoring, and (v) training and systems monitoring to ensure continued security and network viability.

The network over which electronic prescribing data will be transmitted and received must be secure, interoperable, and HIPAA-compliant. The items and services identified above are vital components of such a network. The Proposed Rule does not provide donors and recipients sufficient comfort that these items and services are excepted non-monetary remuneration. Bluegate respectfully request that CMS revise the Proposed Rule to ensure that the provision of these express items to physicians who do not currently possess them is permitted.

2. "Used Solely"

The Proposed Rule require that items and services provided must be "used solely" for the transmission or receipt of electronic prescribing information. Bluegate assumes that CMS is adhering to Congress's mandate that the items and services provided under the Congressionally mandated Stark Law exception be used solely for this purpose, and that CMS does not believe it has the latitude to extend this Congressionally mandated exception to cover other items or services. Bluegate makes this assumption in large based on comments at 70 FED REG 59185, where CMS posits that hardware and connectivity services can be used for the receipt and transmission of a wide range of information services, and that many physicians would prefer to use a single connectivity service for all electronic communications. Bluegate strongly agrees

with this contention. In the event CMS believes it has the latitude to extend the congressionally mandated exception, we would urge that it revise this element of the proposed exception to permit the provision of items and services which are required to permit the physician to engage in electronic prescribing, provided a substantial use of such items and services is electronic prescribing.

To the extent CMS believes it lacks this authority, Bluegate strongly supports CMS's proposal to use its authority to create an additional exception under the Stark Law to protect the provision by qualified donors to physicians of hardware and connectivity services that are used for more than one function, so long as the substantial use of the item or services is to receive and transmit electronic prescription information. Bluegate submits that the adoption of this proposed rule is essential to promoting the rapid growth of a suitable network infrastructure to permit electronic prescribing. It is doubtful that a physician office is interested in receiving isolated hardware, software, internet connectivity, and related services and training for use only for electronic prescribing, since the Proposed Rule would require that the physician also maintain redundant hardware, software, and internet connectivity as well as related training and ongoing support to engage in electronic communications other than electronic prescribing. The cost of educating personnel and support staff, and the cost of maintaining and housing redundant network infrastructure, hardware, and software, would defeat any cost savings provided to a recipient for donated items and services.

Further, while a physician is not likely interested in redundant internet connectivity, the electronic network needed for electronic prescribing must be secure, interoperable, and HIPAA compliant, attributes which most physician office electronic networks do not currently possess. By requiring that a donated network with these attributes be used solely for electronic prescribing, this element would require a physician to absorb monthly costs to maintain a second internet connection at a combined cost substantially higher than the cost of a single secure, interoperable and compliant network connection. This would in fact hinder the donation of suitable and appropriate network connectivity, an absolutely necessary component to permitting a physician to engage in secure, interoperable, and compliance electronic prescribing. For these reasons, Bluegate respectfully requests that CMS revise the Proposed Rule, or alternatively create a new Stark Law exception, to permit the provision of items and services (including those discussed in Section II.A.1. above) which are required to permit the physician to engage in electronic prescribing, provided a substantial use of such items and services is electronic prescribing.

3. Other Conditions

As discussed in Section I above, donated items and services that potentially can be used for electronic prescribing cannot actually be put to that use unless the recipient in question currently utilizes or expects to gain access to a secure, interoperable, and compliant electronic network. Such a network is the backbone to any electronic prescribing network or system. For this reason, Bluegate believes that a prerequisite to the provision of any items and services under this exception should be that the recipient in question either possess, or will be obtaining in connection with the receipt of the donated items or purchases, internet connectivity which will permit the recipient to engage in electronic prescribing in a secure, interoperable, and compliant manner. This safeguard will ensure that expensive hardware, software, and other items or services will not be donated to a recipient until and unless the recipient is able to utilize such items and services for the purposes set forth in the exception.

B. Pre-Interoperability Electronic Health Records Exception: §411.357(w)

1. Covered Technology

CMS proposes to protect only electronic health records software, and then only software that is essential to and used solely for the transmission, receipt, or maintenance of electronic health records, subject to certain additional conditions. Bluegate is mindful that CMS is currently contemplating the adoption of a separate Stark Law exception which would permit the donation of hardware and internet connectivity that is used for more than one function, so long as a substantial use of the item or services is to receive or transmit electronic prescription information. Bluegate strongly supports adoption of such an exception.

Absent the adoption of such an exception, Bluegate would urge that the covered technology under this proposed exception be expanded from simply software to include the following items and services: (i) broadband internet connectivity, (ii) network infrastructure, including hardware and software, (iii) network security, including firewalls, anti-virus software, and hardware protection, (iv) HIPAA compliant security and monitoring, and (v) training and systems monitoring to ensure continued security and network viability. Bluegate is unable to identify a risk of abuse in permitting the provision of these items that does not also apply to permitted software. Further, in the absence of these items, a physician that has been provided the non-monetary compensation permitted by this exception (software) will be unable to utilize it to engage in electronic prescribing or electronic health record communications. Bluegate urges CMS to either revise the Proposed Rule to permit the provision of these items, or alternatively to create the new contemplated exception for hardware and internet connectivity and adopt it concurrently with the Proposed Rule.

2. Used Solely

Bluegate is concerned that the requirement that the covered technology be used solely for the transmission, receipt, or maintenance of patient's electronic health records will severely curtail if not eliminate donations of covered technology. Indeed, this requirement is even potentially at odds with the requirement under this same exception that the donated electronic health records software have an electronic prescribing component. For the reasons discussed above, principally at Section II.A.2., Bluegate would urge the revision of this element to permit the provision of items and services which are required to permit the recipient to utilize an electronic health record platform, provided a substantial use of such item or service is electronic health records.

C. Post-Interoperabilty Electronic Health Records Exception: §411.357(x)

In this exception CMS still proposes to protect only software, and then provided that core functions of the software are electronic health records and electronic prescribing. Bluegate is mindful that CMS is currently contemplating the adoption of a separate Stark Law exception which would permit the donation of hardware and internet connectivity that is used for more than one function, so long as a substantial use of the item or services is to receive or transmit electronic prescription information. Bluegate strongly supports adoption of such an exception. For the reasons discussed in Section II.B. above, absent the adoption of such an exception, Bluegate would urge that the covered technology under this proposed exception be expanded

Bluegate also notes that this exception deviates does not require that items and services be used solely to receive, transmit, and maintain electronic health records. Bluegate agrees with this provision, and presumes this requirement has been removed because the exception will not take effect until after the Secretary has adopted product certification criteria, which the Secretary expects will include a standard requiring that the items and services provided be used appropriately for protected purposes.

III. CONCLUSION

Bluegate wishes to thank CMS for this opportunity to provide comments regarding the Proposed Rule. Bluegate is committed to assisting in the development of processes and procedures that facilitate the development and utilization of a secure, interoperable, reliable and compliant National Health Information Network. We believe the proposed comments included herein further that goal.

If you have any questions about the comments we have submitted, we would be happy to discuss them with you.

Sincerely,

William E. Koehler,
President and Chief Operating Officer

/enclosures

ALLIANCE

The National Alliance for
Health Information Technology

December 8, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1303-P
P.O. Box 8010
Baltimore, MD 21244-8010

Proposed Regulation at 42 CFR Part 411
Medicare Program; physicians' referrals to health care entities with which they have financial relationships; exceptions for certain electronic prescribing and electronic health records arrangements

The National Alliance for Health Information Technology (the "Alliance") is a non-profit association of parties interested in bringing about improvements in health care through the use of information technology (IT). Our 110+ member organizations represent a wide range of health care interests, including hospitals, physicians, IT vendors, consultants, employers, and payors. Our ultimate purpose is to help bring about fundamental change to our nation's healthcare system through improvements in quality, increased efficiency, and reduced costs. Health IT is a vital tool in attaining those ends.

The Alliance supports the intent of section 1877 of the Social Security Act. The so-called "Stark Law" (hereinafter referred to as "Stark") prohibits physicians from making referrals to entities for certain designated health services paid by Medicare if the physician or an immediate family member has a financial relationship with that entity. We also support the ban on entities that receive such a referral from submitting a claim to Medicare for those services.

At the same time, Stark must be viewed through the longer lens of its overall policy objectives, which are to reduce the over-utilization of healthcare services, reduce unnecessary spending and promote consumer choice and access to quality healthcare. [61 Fed. Reg. 69,060, 69,061.] The Department of Health and Human Services, along with CMS, has initiated a national health care information technology agenda to achieve these same objectives. The guiding principle of that agenda is interoperability.

Secretary Leavitt advanced this guiding principle in a statement before the U.S. Senate Committee on the Budget on July 20, 2005. Referring to President Bush's call in April 2004 for electronic health records (EHRs) within 10 years, Secretary Leavitt said, "The goal can be met, but there are major challenges to be faced, and the path forward requires a concentrated nationwide effort to achieve widespread adoption of interoperable EHRs."

Secretary Leavitt's comment affirms the position taken in January 2005 by National Health Information Technology Coordinator Dr. David Brailer, who wrote that "interoperability is a fundamental requirement for the health care system to derive the societal benefits promised by the adoption of electronic medical records." Providers, payers and policy makers all agree that interoperable health care information systems will improve the safety and quality of healthcare delivery, while making the overall health care system more efficient.

The exception created for electronic prescribing is mandated by the Medicare Modernization Act (PL 108-173) to promote the dissemination of health care IT items and services. Providing this exception will advance a key objective of the Act and represent an important step forward in reducing medication errors and promoting efficient health care. However, in promoting the adoption of technology solely for electronic prescribing, the critical goal of interoperability may be compromised. The proposed regulations struggle on the false choice of promoting adoption or promoting interoperability. Both can – and should – be promoted simultaneously.

The Secretary must create exceptions to Stark that are consistent with the law's objectives of reducing the over-utilization of health care services, reducing unnecessary spending and promoting consumer choice and access to quality health care. Specifically, those exceptions should:

- Promote the interoperability of consumers' healthcare information;
- Reduce (and certainly not increase) administrative costs;
- Provide access to all the information needed by physicians to evaluate alternative drug therapies, to identify potential drug-drug interactions, and to improve safety, quality and efficiency of patient care.

Creating exceptions that segment information, make it more difficult for prescribing physicians to access critical information about a patient's medical history or are inconsistent with other standards adopted by the health care field would be inconsistent with the overall purpose of the Medicare Modernization Act. And it would be contrary to the Secretary's own goal of widespread adoption of interoperable electronic health records.

As noted in the comments that follow, we do not believe the regulations, as proposed, advance the key objective of interoperability. In fact, the proposed exceptions work against the stated goals of fostering cooperation between potential donors and physicians to achieve interoperability. We also observe that

the proposed regulations do not create an environment that will encourage the adoption of EHR systems. The express purpose of the proposed exceptions to Stark should be to create clear cases in which health IT can be donated to physicians without fear of violating federal law. However, the proposed exceptions create more uncertainty about what is permitted without eliminating barriers to investment in health care IT.

A less confusing exception would promote the widespread adoption of health IT to improve health care delivery and quality of care and at the same time further the goals laid out in Stark. Interoperable health care information systems allow immediate sharing of information necessary for delivering high quality care to patients and, as consistent with existing legal requirements, appropriate for informing enforcement officials about referral patterns." As CMS Administrator Dr. Mark McClellan stated in announcing the proposed regulations, "Restrictions on relationships between physicians and other health care entities are very important for assuring that Medicare dollars are spent appropriately, **but they were never intended to stand in the way of bringing effective electronic health care to patients."** (HHS press release of October 5, 2005. *Emphasis added.*)

Congressional members assigned as conferees to the Medicare Modernization Act noted their intention that "prescribing health care professionals . . . have ready access to neutral and unbiased information on the full range of covered out-patient drugs available." [H-Report 108-391, at page 455.] The conferees' report directed the Secretary, in adopting standards to promote electronic prescribing, to select standards that are "consistent with the objectives of improving patient safety and the quality and efficiency of patient care, . . . [do] not impose an undue administrative burden on prescribing physicians and pharmacists . . . [and that are] compatible with . . . other health information technology standards." *[ibid]*

Perhaps most importantly, the objectives of Stark must be weighed against the potential to save thousands of lives. In 1999, the Institute of Medicine (IOM) posited the oft-cited statistic that as many as 98,000 people die annually from preventable medical errors. The IOM also identified health IT as an important tool to reduce the number of medical errors. Technology's potential as a tool to improve the quality of patient care is undeniable and must be taken into account in laws that limit the dissemination of health care items and services. To focus solely on the potential for fraud and abuse is to see only half the picture. The other half of the picture depicts a confirmed ability to improve the quality of health for millions of Americans.

Our comments are consistent with both the objectives of Stark and better health care for all Americans through the adoption of IT as described by President Bush and Secretary Leavitt.

Specific comments relating to:

"Pre-Interoperability Electronic Health Records Exception: section 411.357(w)" and "Post-Interoperability Electronic Health Records Exception: section 411.357(x)"

Pre- and Post-Certification

It should be noted that the proposed rule refers to "Electronic health records items and services that are not certified" (proposed section (w)) and "Certified electronic health records items and services" (proposed section (x)) while the preamble refers to these sections as "pre-interoperability" and "post-interoperability." There are significant distinctions between interoperability and certification. For example, the Certification Commission for Health Information Technology (CCHIT) in its RFP with HHS is working to apply certification criteria beyond interoperability to include security and functionality. Although not defined in the regulation, we assume "certification" to encompasses interoperability, security and functionality.

There are several levels of interoperability that will evolve and expand over time, but none will occur overnight. For example, today it would be accurate to say that two fax machines are "interoperable" if they can send and receive messages from one another. While some level of interoperability already exists in health care, like that of the two fax machines, interconnections such as these will continue to evolve and improve, becoming more interoperable over time. The type of interoperability envisioned and desired by most in the health care setting would encompass not only the ability to send and receive data but also to change, process, and act upon that data. When Automated Teller Machines (ATMs) first came out, consumers were not able to use their debit or credit cards at another bank's ATM. Over time, banks became more interconnected and today, most consumers can use their bankcard virtually anywhere in the world. Similarly, CCHIT expects to continually increase the level of expectation relating to interoperability over time. For example, CCHIT may at first certify an EHR system for a limited number of functions that require interoperability, perhaps e-prescribing or the exchange of immunization records between two EHR systems. Next, it might add to the certification process the exchange of lab results, public health reporting and radiology images. As standards mature and data becomes more consistent, interoperability will become the norm instead of the exception.

The proposed regulations provide for two additional regulations issued under the Secretary's discretionary authority under section 1877 (b)(4) of the Act. These are sections (w) for pre-certification and section (x) for post-certification in the proposed rule. However, certification for interoperability has not yet been established.

The work of CCHIT provides a good illustration of the complexity of identifying criteria for certification. The CCHIT certification process requires certain health care IT products be in compliance with relevant standards relating to functionality, security and interoperability. In its inaugural certification

endeavor, CCHIT indicated that it would certify electronic health records used in the ambulatory setting. In defining that product, however, CCHIT specifically determined that electronic prescribing software was a component of an electronic health record, and not, on its own, a certifiable product. If, indeed, the intent is to promote the immediate dissemination of health IT systems, relying on or deferring to yet-to-be-determined criteria is not the best approach.

The most recent exception issued under the Secretary's discretionary authority allows for the donation of IT as long as it's provided on a community-wide basis (42 CFR section 411.357 (u)). This exception has been widely viewed as unworkable due to the lack of clear guidance as to what constitutes a "community." That exception, although ambiguous in its definition, does not apply any pre-and post-certification criteria. Clearly, the concerns identified in the current proposed regulation were not evident in the community-wide exception, nor was the assumption that certification would reduce the likelihood of fraud. The preamble of the proposed pre- and post-certification provisions posits that the donation of items and services increases the likelihood of fraud without any supporting evidence. While we agree that oversight is necessary, we disagree with the underlying premise that the donation of heath care IT items and services are inherently ripe for fraud and, therefore, require additional criteria than those contained in other exceptions established by Congress and the Secretary.

Recommendation

We recommend that the proposed pre- and post-certification regulations be replaced with a single, more immediate and workable exemption. Donors and recipients alike will find the distinctions made between pre- and post-certification exception confusing at best and, more importantly, unworkable. An alternative approach would be to have the Secretary condition the ongoing use of the exception on whether the items being donated are capable of exchanging health care information in compliance with applicable standards once adopted by the Secretary. In that way, the exception is more immediate and less confusing while at the same time putting donating entities on notice that compliance with the Secretary's standards is imminent and ongoing. In developing any applicable interoperability standards, an alternative would be to apply the following guidelines that would be required as a condition of future eligibility for an exception:

- The standard is widely accepted within the industry and has sufficient industry experience to ensure successful implementation;
- The standard is necessary to improve quality of care, patient safety or provide greater administrative efficiencies; and
- A cost and benefit analysis for requiring the standard as a condition of the exception has been conducted.

These conditions would, of course, require implementation guidelines and appropriate time lines for adoption.

Specific comments relating to:
"Electronic Prescribing Exception: Section 411.357(v)"

"Used solely"

The proposed regulation requires that for donated items and services to be eligible for an exception, they must be necessary and "used solely" to transmit and receive electronic prescription drug information. While we recognize that this requirement mirrors the language in the Medicare Modernization Act of 2003 (P.L. 108-173), it will force donating entities to unbundle IT products. That is, most electronic prescribing systems contain additional features that support the operation and management of a physician practice, such as billing and scheduling. Requiring donating entities to strip away those additional functions will make these products less attractive to physicians and physician practices and will defeat the goal of interoperability.

In addition, physicians who currently use computers to perform basic office management functions will be required to maintain two or more separate and potentially incompatible systems: one for electronic prescribing and one for office management. More importantly, the proposed rule suggests that "used solely" would not include the use of robust clinical support tools such as drug-to-drug interactions, drug-to-lab analysis, or prescription data analysis. These are vital tools in providing quality patient care and should be allowed to be part of an electronic prescribing system.

Under the proposed rule, two or more systems would be required because donors are permitted to provide multi-functional IT only under the proposed pre- and post-certification regulations, but not under the e-prescribing exception. Moreover, under the proposed regulations, physicians cannot "intentionally divest" themselves of equivalent systems in order to receive new, upgraded technology provided by eligible donors.

Among the many benefits of the adoption of health care IT are improvements in workflow efficiency, which, in turn, can have a positive impact on patient care. Requiring the use of two computer systems or two handheld devices will disrupt workflow rather than improve it.

Recommendation

We recommend that the Office of the Secretary use its discretionary authority to allow for the provision of functional products that include features such as billing and scheduling. This will help stimulate adoption without forcing physicians to choose between a single-function electronic prescribing system and having to operate and maintain two separate and unconnected systems, which

defeats the purpose of furthering interoperability. However, the proposed rules for pre- and post-electronic health records systems actually require the bundling of electronic prescribing technology. The bundling of clinical support and medical management tools are appropriate in all donation settings. At a minimum, the rule should be clarified to ensure that the use of drug-to-drug interaction programs, formulary information, prescription analysis, and other pharmacy tools are allowed.

Specific comments relating to:
"Pre-Interoperability Electronic Health Records Exception: section 411.357(w)" and "Post-Interoperability Electronic Health Records Exception: section 411.357(x)" and "Electronic Prescribing Exception: Section 411.357(v)"

(1) Financial limit on the amount of donated IT systems

In one section of the preamble, there is a call for assistance in developing and defining a limitation, or cap, on the *value* of donated IT items and services. However, in another section, there is a request to help establish and define a cap on the *amount* of donated items and services provided. Because the amount or cost of donated items and services are often not synonymous with their value, it should be clarified that providers may be allowed to determine fair market value based on their costs of the donated technology. Requiring providers to determine the value of the technology to the physician-recipient would be time consuming and confusing because physicians may place a different value on the technology based on any number of factors.

This distinction aside, a cap on either the amount or the cost of donated items and services could discourage early donations given that an early donating entity could reach its limit after the first donation and, therefore, be unable to provide additional items and services in the proposed post-certification environment. Likewise, eligible recipients of donated items and services are unlikely to accept early donations knowing they may not be able to receive additional items and services as interoperability and technology evolve. As noted in the preamble to the proposed rule, the cost of health care IT will likely decrease over time. However, reducing the cap, as suggested in the preamble, will stifle early adoption because both donors and recipients will be concerned about future limitations.

There is also the question of on-going maintenance and support. Would these services be included in the cap? If not, physicians may be unwilling to pick up the additional expense, particularly in the absence of a financial incentive to do so. After all, a major purpose for providing the exception is "... to encourage the adoption of such technology through this proposed rulemaking." Establishing an arbitrary limit on the value of the items and services donated will discourage adoption in the absence of some other financial incentive for physicians.

Recommendation

We recommend is that there be no cap or, if necessary, a cap that provides sufficient flexibility to encourage early adoption. In addition, any cap should take into account on-going maintenance and support services, such as help desk. Both donors and recipients must have a clear and easily understood framework of how value is determined. In addition, if there is a cap, providers should be allowed to determine fair market value based on their costs of the donated technology.

(2) Physician certification

The proposed regulation requires that the arrangement between the donating entity and the physician receiving the items and services be in writing and include, among other things "...a certification by the physician that the items and services provided are not technically or functionally equivalent to items and services he or she already possesses." The preamble states the physician "...must update the certification prior to the furnishing of any necessary upgrades or item and services not reflected in the original certification. " This suggests that physicians are, or need to become, proficient at identifying and distinguishing various levels of computer hardware and software. Even individuals who may be computer savvy could have difficulty with this requirement. For example, is Microsoft Word the technical or functional equivalent of Corel WordPerfect? This is a rather superficial example, and the requisite level of expertise will only increase when getting into areas of encryption and data sharing. Furthermore, what constitutes equivalency between two products? How different must one product be from another to not be considered "equivalent?" If one product has 25 functions and the one being donated under the exception has 24 or 26 functions, would those be considered "not equivalent?"

Recommendation

We recommend eliminating the requirement that physicians certify that they do not possess technical or functional equivalent items and services. At the least, it should be predicated on a good-faith standard for compliance. In addition, the term equivalent should be clearly defined.

(3) Permissible Donors and Recipients

The proposed regulation identifies specific entities that may be exempt from providing items and services without violating Stark. They are limited to: (1) hospitals to their medical staffs; (2) group practices to their physician members; (3) Prescription Drug Plan sponsors to their physicians; and (4) Medicare Advantage organizations to their physicians.

In order to promote the rapid adoption of health information technology, the rule should have an expanded list of eligible donors. The greater the number of health care entities that are allowed to provide items and services, the greater the increase in demand for, and supply of, electronic health record systems. Limiting the number of eligible donors will result in pockets of health care IT adoption, which will work to the advantage some patients but not others.

The preamble to the proposed rule states that CMS does "...not believe that providers and suppliers of ancillary services, such as laboratories, are well-positioned to advance the goal of widespread use of interoperable electronic health records for patients, nor would have the same interest in doing so." However, regional electronic health record systems require a reliable, scalable, and open infrastructure that can support tens of thousands of concurrent users and facilitate interoperability. Laboratory tests and results comprise roughly 60% of existing electronic health records. (Source: The Value of Diagnostics: Innovation, Adoption & Diffusion into Health Care, The Lewin Group, July 26, 2005). Laboratory networks are capable of supporting thousands of concurrent users and already interface with most major hospital and physician electronic health record systems. Furthermore, integrated laboratory and electronic prescribing products provide physicians with the ability to compare gaps in care with clinical guidelines, and to track and report results as part of a physician quality incentive and pay-for-performance programs.

In addition, a prominent type of entity in health care known as an Integrated Delivery System (IDS) would be ineligible as a donor under the proposed rule. An IDS is a system of provider organizations including a parent entity that owns or controls one or more hospitals and at least one or more the following: network providers, an entity that operates and manages the network providers; and/or a physician-hospital organization or physician organization. Because many of the contracts with the IDS parent entity and payor (e.g., an IDS and HMO), involve physicians who are not part of the hospital's medical staff, under the proposed rule, they would not be eligible to receive donated items and services despite the obvious benefits of their having access to health care IT items and services. Broadening the rule to permit IDS network physicians who participate with the IDS for managed care contracting would be consistent with the objective of encouraging IT adoption as broadly as possible.

Recommendation

We recommend that clinical laboratories should be included in the list of permissible donors. We also recommend that permissible donors should include any component of an IDS. Likewise, physicians who are network providers should be included in the list of eligible recipients of health care items of services.

(4) Interoperability

In order to qualify under the proposed exception, a donating entity may not take "...any actions to disable or limit that interoperability or otherwise impose barriers to compatibility." This requirement should be clarified because a donating entity may simply be sharing items and services that are compatible with the system(s) it operates but are not necessarily compatible with other operating systems. For example, a donating entity may utilize Microsoft Outlook for scheduling in all of its operating systems and thus include that program in the items donated. However, because the donating entity did not include WordPerfect in the items provided, it could arguably have limited interoperability.

Recommendation

We recommend that the prohibition against disabling or limiting interoperability require a specific action or actions by the donating entity and not encompass the mere provision of items and services that are compatible with only the donating entity.

In addition, the preamble defines interoperability "...to mean the ability of different information systems, software applications, and networks to communicate and exchange information in an accurate, secure, effective, useful, and consistent manner." Earlier this year, the Alliance, along with its members and other stakeholders in the industry, developed a definition of interoperability for use in policy and legal discussions of health IT. This definition has been endorsed by over 50 leading organizations including the American Medical Association, Blue Cross Blue Shield Association, General Motors, JCAHO, and Johnson & Johnson Healthcare.It reads:

> "In healthcare, *interoperability* is the ability of different information technology systems and software applications to communicate, to exchange data accurately, effectively, and consistently, and to use the information that has been exchanged."

Because this definition was developed with the input of stakeholders from across healthcare and has been endorsed by a broad range of organizations, its use in policymaking will further standardize the language surrounding these issues and reduce the kind of confusion that has already delayed rapid adoption of health IT, and strengthen the public-private collaboration already underway.

Recommendation

We recommend that the widely-endorsed consensus definition of interoperability be adopted.

(5) Covered Technology

The proposed regulation narrowly defines covered technology to include EHR software and related training, but not administrative functions or

connectivity. While software and directly related training clearly are important to physician adoption of EHRs, they are not sufficient. Physicians often do not have the technical knowledge or resources to obtain and manage all of the necessary items, which is often why they have not pursued acquiring health IT. Not being allowed to incorporate or interface existing and evolving technologies will discourage adoption. Moreover, health care IT is intended to increase connectivity (e.g., transmit and receive medical images) that can be vital to patient care. Physicians need support to ensure these functions are achieved and optimized on an on-going basis.

Recommendation

We recommend that covered technology should include multifunctional connectivity and related software and hardware. This should include software interfaces, upgrades to the initial software, and ongoing technical maintenance and support software.

(6) Other requirements – Avoiding increased referrals

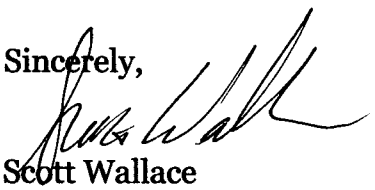
As noted in the preamble, the benefits of health care IT items and services include fewer medical errors, reduced costs and improved quality of care for patients. All of these could have the beneficial effect of encouraging physicians to refer patients to hospitals that have adopted electronic health care systems. That is, the value to the physician is improved patient care and improved efficiency in operating his or her office, but a permissible donor could find itself outside the parameters of the exception because the donated items and services had the incidental impact of an increase in referrals. Clearly, physicians today refer to hospitals based on any number of criteria. If physicians are able to treat more patients in a more effective (i.e., improved quality of care) and efficient manner because they are able to take advantage of donated IT systems, patients will be much better off.

Recommendation

We recommend that any incidental increase to the volume of referrals that are the result of increased quality and patient care be expressly permitted. Stark was contemplated and debated at a time when the nation was not on the cusp of such a monumental change in health caredelivery. In the absence of evidence of fraud, incidental increases in referrals are, in fact, necessary to help drive market forces to spur adoption and, as such, should not be viewed as *per se* violations.

The Alliance is available to provide any additional information about the proposed regulation or answer any questions you may have about our specific comments. Please feel free to contact me directly at (312) 422-2181 or swallace@nahit.org, or Bill Head, Vice President of Policy and Government Affairs, in our Washington D.C. office at (202) 898-6370 or bhead@nahit.org.

Sincerely,



Scott Wallace
President and CEO

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VHA®

December 9, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Attention: CMS-1303-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-8010

Re: CMS-1303-P – Comments Regarding Proposed Stark Law Exceptions for Certain Electronic Prescribing and EHR Arrangements

Dear Dr. McClellan:

On behalf of VHA Inc. ("VHA"), I am writing to provide comments on the proposed rule to establish three exceptions to the federal physician self-referral ("Stark") law for certain electronic prescribing and electronic health records ("EHR") arrangements ("Proposed Exceptions"). The proposed rule was published by the Centers for Medicare & Medicaid Services ("CMS") in the October 11, 2005 Federal Register, 70 Fed. Reg. 59182.

VHA is a national alliance of leading not-for-profit hospitals and health care organizations that work together to improve the health of the communities they serve. VHA delivers industry leading supply chain management services and enables regional and national member networks to improve clinical and operational performance and to drive sustainable results. Based in Irving, Texas, VHA has 18 local offices serving more than 2,400 health care organizations across the United States.

I. General Comments

As CMS notes in the preamble to the Proposed Exceptions, the "implementation of electronic health information technology is a compelling national priority to improve our healthcare system." 70 Fed. Reg. at 59187. If anything, this may be an understatement. As part of the Medicare Modernization Act, Congress created the Commission on Systemic Interoperability. On October 25, 2005, the Commission issued its report, *Ending the Document Game: Connecting and Transforming Your Healthcare Through Information Technology* ("CSI Report"). The CSI Report concludes, among other things, the following:

- "In 2000, the Institute of Medicine (IoM) estimated that between 44,000 and 98,000 Americans die each year from preventable medical errors," and "[t]he lack of immediate access to patient healthcare information is the source of one-fifth of these errors." CSI Report at 11.

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- "Under the current paper-based system, patients and their doctors lack instant, constant access to medical information. As a result, when a patient sees more than one doctor, no doctor knows exactly what another doctor is doing, or even that another doctor is involved. The consequences range from inconvenient to critical or even fatal." CSI Report at 11.

- In addition, "[h]andwritten records—most notoriously, prescriptions—are easily misread, causing potentially life-threatening mistakes. Similarly, analysis of large numbers of paper records is impossible, denying the public the benefits of early warnings of dangerous trends in disease or bioterrorism, and other research-driven efforts." CSI Report at 12.

- "These problems and others are well addressed by a connected system of healthcare information, one that is referred to in this report as interoperable. The benefits of this interoperable system will extend to both patients and healthcare providers and may be categorized as promoting convenience, confidentiality, access, and quality of care." CSI Report at 12.

- In sum, "[t]he quality of our healthcare, on both societal and individual levels, is suffering from the lack of a connected system of healthcare information. The cost comes in injury, wasted resources, and lost lives." An "interoperable system of electronic healthcare information" is a goal that "can be reached, and its benefits are worth the effort that will be required. The evidence cited in this report compels action to achieve an interoperable health information technology system in the United States. Lives are in the balance." CSI Report at 14-15.

As CMS notes in the preamble, the agency must promote the implementation of a connected system of healthcare information without protecting arrangements that "influence inappropriately clinical decision-making," or are otherwise abusive. 70 Fed. Reg. at 59187. With respect to the issue of program abuse, in discussing its authority to promulgate Stark law exceptions, CMS has made it clear that it will not "limit the exceptions to those situations that pose no risk of fraud or abuse." 66 Fed. Reg. 856, 863 (Jan. 4, 2001). Instead, it will protect "arrangements that, in most situations, would not pose a risk," and rely on other fraud and abuse laws to address any "residual risk." 66 Fed. Reg. at 863.

Moreover, it should be emphasized that unlike the typical case, where CMS is called upon to develop an exception for an arrangement that is, at best, benign from a public policy standpoint (e.g., arrangements covered by the Stark law's medical staff incidental benefits exception), as reflected in the CSI Report (and elsewhere) there is a compelling need — recognized by both Congress and the President — for the rapid and widespread adoption of electronic prescribing and EHR technology.

For the reasons set forth below, VHA does not believe that the Proposed Exceptions, as drafted, strike the necessary balance between, on the one hand, promoting the adoption of electronic prescribing and EHR technology and, on the other hand, ensuring that the arrangements at issue do not pose a risk of program abuse. More specifically, and for the reasons discussed below, VHA believes:

- that the requirements set forth in the Proposed Exceptions are so numerous, so onerous, and so restrictive that, rather than promoting the adoption of electronic prescribing and EHR technology, they are likely to inhibit such adoption, and

- concomitantly, that many of these requirements are not necessary to ensure that the donation of electronic prescribing and EHR technology will not pose a risk of program abuse.

II. Pre-Interoperability Electronic Health Records Exception: § 411.357(w)[1]

CMS' proposed Pre-Interoperability Exception would protect "software" and "directly related training services" that are "necessary" and used "solely" to "receive, transmit, and maintain" EHR, provided 10 substantive requirements are met. § 411.357(w) (proposed). (An eleventh requirement, § 411.357(w)(11) (proposed), relates solely to the Exception's sunset provision.)

For the reasons set forth below, VHA believes that the inclusion of seven of these 10 requirements — which we will refer to as the "core pre-interoperability requirements" (or "core requirements") — together with a series of modifications to certain other provisions of the Proposed Exception, will (1) be more than sufficient to ensure that EHR technology arrangements do not pose a risk of program abuse and (2) increase the likelihood that donors and physicians will take advantage of the Exception and, therefore, that EHR technology will be adopted in a more timely and comprehensive manner.

A. Core Pre-Interoperability Requirements

The first three core pre-interoperability requirements relate to the principal policy objective of the Stark law, which is to prevent arrangements that give physicians a financial incentive to order certain "designated health services" (including hospital inpatient and outpatient services) that are not medically necessary. 63 Fed. Reg. 1659, 1662 (Jan. 9, 1998).

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[1] All citations are to "42 C.F.R." unless otherwise indicated.

- The first core requirement essentially provides that a donor (such as a hospital) cannot make the provision of EHR technology to a physician contingent on his or her referral of patients or business to the donor. § 411.357(w)(4) (proposed).

- The second core requirement — which is closely related to the first — essentially provides that a physician cannot make his or her referral of patients or business to the donor contingent on its provision of EHR technology to the physician. § 411.357(w)(3) (proposed).

- The third core requirement — which is closely related to the first two — provides that the arrangement cannot violate the federal health care program anti-kickback law, or any Federal or State law or regulation governing billing or claims submission. § 411.357(w)(10) (proposed).

The fourth and fifth core requirements relate to documentation and certifications of compliance. Specifically:

- The fourth core requirement would require that the EHR arrangement be set forth in a written, signed agreement that (1) covers and specifies all of the EHR items or services being provided by the donor to the physician, (2) specifies the value of those items and services, and (3) includes a certification by the physician that the items and services are not technically or functionally equivalent to items and services that the physician already possesses. § 411.357(w)(5) (proposed).

- As an added safeguard, the fifth core requirement provides that the Exception will not apply if the donor knew or should have known that the physician's certification notwithstanding, the physician in fact possessed items and services that were technically or functionally equivalent to those furnished by the donor. § 411.357(w)(6) (proposed).

The final two core requirements restrict the ability of donors to modify or limit the use of donated technology. Specifically:

- The sixth core requirement provides that if the donated items or services "can be used for any patient without regard to payor status, the donor may not restrict or take any action to limit the physician's right or ability to use the items or services for any patient." § 411.357(w)(7) (proposed).

- The seventh core requirement provides that the donor cannot "limit or restrict unnecessarily the use or compatibility of the items or services with other

electronic health records items or services or electronic health information systems." § 411.357(w)(2) (proposed).

VHA believes that the first three core requirements alone — which effectively (1) prohibit donors from paying for referrals, (2) prohibit physicians from soliciting such payments, and (3) prohibit both parties from violating the anti-kickback law — are sufficient to ensure that the arrangements at issue will not pose a risk of program abuse. That is, assuming an EHR arrangement meets these three core requirements, the arrangement — by definition — cannot serve an improper purpose under the Stark law.

A hypothetical helps demonstrate the point. Assume a hospital donates EHR technology to a physician. Assume further that this arrangement complies with the first three core requirements discussed above. That is:

- In deciding whether to provide technology to the physician, the hospital did not take into account the volume or value of referrals or other business generated by the physician for the hospital.

- In deciding the amount of technology to provide to the physician, the hospital did not take into account the volume or value of referrals or other business generated by the physician for the hospital.

- In deciding the nature of the technology to provide to the physician, the hospital did not take into account the volume or value of referrals or other business generated by the physician for the hospital.

- The physician did not make the receipt of the technology a condition of referring patients to (or otherwise doing business with) the hospital.

- The physician did not make the amount of the technology a condition of referring patients to (or otherwise doing business with) the hospital.

- The physician did not make the nature of the technology a condition of referring patients to (or otherwise doing business with) the hospital.

- The arrangement does not violate the federal health care program anti-kickback law. That is:

  - The hospital did not provide the technology to the physician in an effort to induce him to (1) refer federal health care program patients to the hospital (2) purchase, lease, or order covered items or services from the hospital,

(3) arrange for such purchases, leases or orders, or (4) recommend such purchases, leases, or orders.

- The physician did not solicit the technology from the hospital in exchange for (1) referring federal health care program patients to the hospital (2) purchasing, leasing, or ordering covered items or services from the hospital, (3) arranging for such purchases, leases or orders, or (4) recommending such purchases, leases, or orders.

Under these circumstances, it is difficult to perceive how the hospital's provision of the EHR technology could possibly pose a risk of program abuse. In any event, when coupled with the remaining four core requirements — which (1) ensure that the physician does not already have the items or services at issue (and, as such, that the EHR technology is, in fact, "necessary") and (2) ensure the hospital does not improperly restrict the interoperability of the technology — the sufficiency of the Exception from a program abuse standpoint is even more compelling.

For these reasons, VHA believes that the remaining three requirements of the proposed Pre-Interoperability Exception, as well as certain other provisions of the Proposed Exception, should be eliminated or modified, as discussed below.

B. Proposed Deletions & Modifications

1. Software/Services

Assuming that the seven core requirements discussed above are met, VHA does not believe that it is necessary or appropriate to limit the types of non-monetary remuneration that may be protected by the Pre-Interoperability Exception to "software" and "directly related training services." Instead, the Exception should protect whatever items or services — including but not limited to hardware, software, connectivity, and equipment installation, training and maintenance services and support — that are, in fact, necessary for a particular physician to "receive, transmit, and maintain" EHR.

Simply put, if a physician does not have, for example, the hardware necessary to operate the EHR technology at issue, it would be neither necessary (from a fraud and abuse standpoint) nor advisable (from an EHR adoption standpoint), to prohibit a donor from providing such hardware to the physician. As CMS notes in the preamble, "there may be particular constituencies, such as rural area providers, that lack sufficient hardware or connectivity services to implement effective electronic health records systems." 70 Fed. Reg. at 59188. Whether a physician is in a rural area, however, should not be determinative. What should be determinative is whether the physician does or does not have "sufficient hardware or connectivity services to implement effective electronic health records systems."

If the physician already has such hardware and connectivity, then the Exception will not be available, because the technology will not be "necessary." If the physician does not have such hardware and connectivity, then there is no good reason — from either a program abuse or EHR technology adoption standpoint — to preclude a donor from providing these items and services to the physician. To the contrary, program abuse will be prevented through compliance with the seven core requirements and, by expanding the categories of EHR-related items and services that may be protected by the Exception, CMS substantially increases the likelihood that EHR technology will, in fact, be adopted by donors and physicians.

Finally, we would note that VHA's proposed approach would be consistent with CMS' existing Stark law exception for community-wide health information systems, which — subject to certain conditions that are similar to the core requirements (e.g., compliance with the anti-kickback law) — protects any "[i]tems or services of information technology" provided by an entity to a physician. § 411.357(u).

2. Used "Solely"

The proposed Pre-Interoperability Exception would apply only to items and services that can be used "solely" to receive, transmit, and maintain EHR; and one of the Exception's requirements specifically provides that protected items and services "do not include any billing, scheduling, or other similar general office management or administration software or services, nor do the services include staffing of physician offices." § 411.357(w)(8) (proposed).

VHA does not believe that it is practical or necessary to limit the types of items or services that can be protected to those that can be used "solely" to receive, transmit, and maintain EHR. As a practical matter, a single integrated product may, for example, include software that can be used both to maintain EHR and to schedule office visits. In connection with the Post-Interoperability Exception (discussed below), CMS states that it "want[s] to ensure that integrated packages that could positively impact patient care are not excluded" from the Exception, provided the "core function" of the items and services are electronic health records. 70 Fed. Reg. at 59190. Given the protections offered by the seven core requirements, VHA believes that this statement should be equally applicable to the Pre-Interoperability Exception.

Finally, our position is, once again, supported by CMS' community-wide health information systems exception, which protects any items or services of information technology, provided they are "principally" used by the physician as part of the community-wide health information system. § 411.357(u)(1).

3. Electronic Prescribing Capability

The proposed Pre-Interoperability Exception requires that the EHR technology contain "electronic prescribing capability that complies with the electronic prescription drug program standards under Medicare Part D at the time the items and services are furnished."

§ 411.357(w)(9) (proposed). While VHA believes that the provision of items and services that include electronic prescribing capability may (and should) be protected by the Pre-Interoperability Exception, VHA does not believe that a donor should be required to include such capability in order for the Exception to apply. Once again, VHA believes that this requirement is not necessary from a fraud and abuse standpoint and, by decreasing donor flexibility, can only serve to inhibit the proliferation of EHR technology, not promote it.

4. Permissible Recipients

Where the donor at issue is a hospital, the only permissible recipients under the proposed Exception would be members of the hospital's medical staff. § 411.357(w)(1)(i) (proposed). CMS suggests, in its discussion of the Electronic Prescribing Exception (discussed below), that the agency intends to "protect donations only to physicians who routinely furnish services at the hospital," and not "remuneration used to induce physicians who already practice at other hospitals to join the medical staff of a different hospital." 70 Fed. Reg. at 59185. VHA does not believe that this requirement is necessary from a fraud and abuse standpoint or advisable from an EHR technology adoption standpoint.

The requirement is not necessary from a fraud and abuse standpoint because — with respect to the inducement issue — one of the core requirements of the Pre-Interoperability Exception already provides that "[n]either the eligibility of a physician for the items or services, nor the amount or nature of the items and services" may be "determined in a manner that is directly related to the volume or value of referrals or other business generated between the parties." § 411.357(w)(4) (proposed). Thus, from a fraud and abuse standpoint, the limitation on permissible recipients is not necessary to achieve its objective. (On a more practical level, to the extent a hospital provides EHR to a physician who is not on the hospital's medical staff, it is highly unlikely that the donation would be intended to induce the physician to make referrals to the hospital or, therefore, that the donation would implicate any of the Stark law's policy objectives.)

The requirement is inadvisable from an EHR technology adoption standpoint because, as CMS notes, hospitals have "a direct and primary patient care relationship" and "a central role in the health care delivery infrastructure" and, as such, "are potentially in a better position [than ancillary services providers] to promote widespread use of [EHR] technology that has the greatest degree of openness and interoperability." 70 Fed. Reg. at 59189. Under these circumstances, it does not make sense to limit the ability of a hospital to offer EHR technology — subject, again, to compliance with the seven core requirements — to as many physicians in the community as possible.

5. Value Cap

Although the Proposed Exception does not include a requirement limiting the value of donated EHR items and services, CMS states in the preamble that it believes that "it would be appropriate to limit the aggregate value of the protected software and directly related training services that a DHS entity could provide to a physician under the exception." 70 Fed. Reg. at 59189. In support of its proposal, CMS states that this "approach is consistent with the purpose of the physician self-referral prohibition and would also minimize any competitive disadvantage for smaller entities that do not have the financial resources or potential volume of technology business of larger chains or organizations." 70 Fed. Reg. at 59189.

VHA believes that the purpose of the Stark law will be amply served through compliance with the core requirements. Indeed, CMS reached the same conclusion with respect to the community wide health information systems exception — as well as the physician recruitment exception, § 411.357(e), and the compliance training exception, § 411.357(o) — none of which (1) require the referring physician to pay fair market value for benefits received from the hospital (or other entity) at issue or (2) place any dollar (or other) limit on the value of the items or services that may be furnished to the referring physician.

Nor does the value of EHR technology support a different result with respect to the Pre-Interoperability Exception. In its Regulatory Impact Statement, CMS estimates "that, at most, each physician would receive a total of $3,000 worth of donated items and services" under all three of the proposed exceptions combined. 70 Fed. Reg. at 59195. Even taking into account the fact that this is an estimate only, and does not include the costs of hardware, connectivity, etc., in many (and perhaps most) cases, the value of the benefits provided to physicians pursuant to recruitment arrangements, for example — in the form of income guarantees and the like — are far greater than this; indeed, they often are well into the six figure category.

III. Post-Interoperability Electronic Health Records Exception: § 411.357(x)

The proposed Post-Interoperability Exception would protect "software" and "directly related training services" that are "necessary" to "receive, transmit, and maintain" EHR, provided 10 requirements are met. § 411.357(x) (proposed). For the reasons set forth below, VHA believes that the inclusion of eight of the 10 requirements — which we will refer to as "core post-interoperability requirements" — coupled with a series of modifications to certain other provisions of the Proposed Exception, will (1) be more than sufficient to ensure that the arrangements at issue do not pose a risk of program abuse and (2) increase the likelihood that donors and physicians will take advantage of the Exception and, therefore, that EHR technology will be adopted in a more timely and comprehensive manner.

A. Core Post-Interoperability Requirements

Six of the seven core pre-interoperability requirements (set forth in Section II.A. above) also are core post-interoperability requirements. (The exception is the requirement that the donor cannot "limit or restrict unnecessarily the use or compatibility of the items or services with other electronic health records items or services or electronic health information systems." § 411.357(w)(2) (proposed).) The two non-"overlap" core requirements are as follows:

- First, the proposed Post-Interoperability Exception provides that the technology at issue must be "certified in accordance with criteria adopted by the Secretary that are in effect at the time of the donation." § 411.357(x)(2). (As noted in the preamble, this certification will include uniform industry standards for interoperability, functionality, privacy and security. 70 Fed. Reg. at 59190.)

- Second, the proposed Post-Interoperability Exception provides that the items and services that are donated may "not include staffing of physician offices" and may not be "used solely to conduct personal business or business unrelated to the physician's medical practice." § 411.357(x)(8) (proposed).

For all of the reasons discussed with respect to the Pre-Interoperability Exception in Section II above, VHA believes that the eight core post-interoperability requirements are more than sufficient to ensure that the arrangements at issue will not pose a risk of program abuse. Indeed, this position is even more compelling with respect to the Post-Interoperability Exception because, as noted above, this Exception will require that all donated EHR comply with uniform industry standards for interoperability. As CMS notes in the preamble:

> Interoperable systems have the technical capacity to transmit and receive information from other devices and applications in a secure and intelligible manner. We believe that interoperability can serve as an important safeguard against fraud and abuse, because a requirement that protected technology be fully interoperable would mitigate the risk that an entity could offer free or reduced price technology to a referring physician as a means of maintaining or increasing that physician's referrals to the entity.

70 Fed. Reg. at 59186. Accordingly, VHA believes that the two non-core post-interoperability requirements of the proposed Exception, as well as certain other provisions of the proposed Exception, should be eliminated or modified as discussed below.

B. Proposed Deletions & Modifications

1. Software/Services

For the reasons discussed in Section II.B.1. above, assuming that the eight core post-interoperability requirements are met, VHA does not believe that it is necessary or appropriate to limit the types of non-monetary remuneration that may be protected by the Post-Interoperability Exception to "software" and "directly related training services." Instead, the Exception should protect whatever items or services — including but not limited to hardware, software, connectivity, and equipment installation, training and maintenance services and support — that are, in fact, necessary for a particular physician to "receive, transmit, and maintain" EHR.

2. Electronic Prescribing Capability

Like the Pre-Interoperability Exception, the proposed Post-Interoperability Exception requires that the EHR technology contain "electronic prescribing capability that complies with the electronic prescription drug program standards under Medicare Part D at the time the items and services are furnished." § 411.357(x)(9) (proposed). Again, while VHA believes that the provision of items and services that include electronic prescribing capability may (and should) be protected by the Post-Interoperability Exception, VHA does not believe that a donor should be required to include such capability.

3. Permissible Recipients

As under the Pre-Interoperability Exception, where the donor at issue is a hospital, the only permissible recipients under the proposed Post-Interoperability Exception would be members of the hospital's medical staff. § 411.357(x)(1)(i) (proposed). For the reasons set forth in Section II.B.4. above, VHA does not believe that this requirement is either necessary or advisable.

4. Value Cap

As in the case of the Pre-Interoperability Exception, CMS states in the preamble that it is considering placing a limit on the value of the items and services protected by the Post-Interoperability Exception. 70 Fed. Reg. at 59191. For the reasons set forth in Section II.B.5. above, VHA does not believe that such a limit is either necessary or advisable.

IV. Electronic Prescribing Exception: § 411.357(v)

The proposed Electronic Prescribing Exception would protect "hardware, software, or information technology and training services" that are "necessary" and "used solely" to "receive and transmit electronic prescription information," provided eight requirements are met.

§ 411.357(v) (proposed). For the reasons set forth below, VHA believes that the inclusion of seven of these eight requirements — which we will refer to as "core prescription requirements" — coupled with a series of modifications to certain other provisions of the proposed Exception, will (1) be more than sufficient to ensure that the electronic prescription technology donation arrangements do not pose a risk of program abuse and (2) increase the likelihood that donors and physicians will take advantage of the Exception and, therefore, that electronic prescription technology will be adopted in a more timely and comprehensive manner.

A. Core Prescription Requirements

Six of the seven core pre-interoperability requirements (set forth in Section II.A. above) also are core prescription requirements. (The exception is the requirement that the arrangement at issue must not violate the federal health care program anti-kickback law, or any Federal or State law or regulation governing billing or claims submission.) The seventh core prescription requirement provides that the items and services at issue must be "donated as part of, or [be] used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are furnished." § 411.357(v)(2) (proposed).

For all of the reasons discussed in Sections II and III above with respect to the Pre- and Post Interoperability Exceptions, VHA believes that the seven core prescription requirements are more than sufficient to achieve CMS' objectives, and that the one non-core prescription requirement, as well as certain other provisions of the proposed Exception, should be eliminated or modified as discussed below.

B. Proposed Deletions & Modifications

1. Hardware/Software/Services

The proposed Electronic Prescribing Exception would limit the types of non-monetary remuneration that may be protected by the Exception to "hardware, software, or information technology and training services." § 411.357(v). In the preamble, however, CMS indicates that it intends for the Exception to cover, "for example, 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." 70 Fed. Reg. at 59184 (emphasis added). For the reasons discussed in Sections II.B.1. and III.B.1. above, VHA agrees that the Exception should be expanded to protect whatever items or services — including but not limited to connectivity, and equipment installation and maintenance services and support (including, for example, a help desk) — that are, in fact, necessary for a particular physician to receive and transmit electronic prescription information.

2. Used "Solely"

The proposed Electronic Prescribing Exception would apply only to items and services that can be used "solely" to receive and transmit electronic prescription information. In the preamble, however, CMS notes that it is "mindful that hardware and connectivity services can be used for the receipt and transmission of a wide range of information services, including, but not limited to, electronic prescription information," and "that many physicians may prefer to use a single, multi-functional device, especially a hand-held, rather than multiple single-use devices." 70 Fed. Reg. at 59185. "Similarly," CMS notes, "many physicians may prefer to use a single connectivity service." 70 Fed. Reg. at 59185.

> Accordingly, we are proposing to use our authority [to promulgate Stark law exceptions] to create an additional exception to protect the provision by DHS entities to physicians of 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.

70 Fed. Reg. at 59185.

For the reasons discussed in Section II.B.2 above, VHA does not believe that it is practical or necessary to limit the types of items or services that can be protected to those that can be used "solely" to receive and transmit electronic prescription information. Accordingly — and consistent with CMS' position in the preamble — VHA believes that protection should be provided for any item or service that is 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."

However, given the regulatory complexity already posed by the Pre-Interoperability, Post-Interoperability, and Electronic Prescribing Exceptions, collectively — coupled with those parallel exceptions under development by the U.S. Department of Health & Human Services Office of Inspector General (with respect to the federal health care program anti-kickback law) — VHA would strongly encourage CMS, to the extent permitted by law, to affect this change as part of the proposed Electronic Prescribing Exception and not as part of (yet) another proposed Stark law exception.

3. Permissible Recipients

As under the Pre- and Post-Interoperability Exceptions, where the donor at issue is a hospital, the only permissible recipients under the proposed Electronic Prescribing Exception would be members of the hospital's medical staff. § 411.357(v)(1)(i) (proposed). For the

reasons set forth in Sections II.B.4. and III.B.3. above, VHA does not believe that this requirement is either necessary or advisable.

4. Value Cap

As in the case of the Pre- and Post-Interoperability Exceptions, CMS states in the preamble that it is considering placing a limit on the value of the items and services protected by the Electronic Prescribing Exception. 70 Fed. Reg. at 59186. For the reasons set forth in Sections II.B.5 and III.B.4. above, VHA does not believe that such a limit is either necessary or advisable.

V. Additional Comments - "Volume or Value" Standard

A. Background

One of the Electronic Prescribing Exception's requirements is that "[n]either the eligibility of a physician for the items or services, nor the amount or nature of the items and services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties." § 411.357(v)(6) (proposed). According to the preamble, compliance with this requirement would not "preclude selection criteria that are based upon the total number of prescriptions written by a physician," but it "would prohibit criteria based upon the volume or value of prescriptions written by the physician that are dispensed or paid by the donor, as well as any criteria based on any other business generated between the parties." 70 Fed. Reg. at 59187.

The Pre-Interoperability Exception has an identical requirement: "[n]either the eligibility of a physician, nor the amount or nature of the items and services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties." § 411.357(w)(4) (proposed). In the preamble, however, CMS does not offer any examples of conduct that would meet (or fail to meet) this requirement.

Finally, the Post-Interoperability Exception has a similar — but not identical — requirement: "[n]either the eligibility of a physician for the items or services, nor the amount or nature of the items and services, is determined in a manner that is directly related to the volume or value of referrals or other business generated between the parties." § 411.357(x)(4) (proposed).

Whereas the Electronic Prescribing and Pre-Interoperability Exceptions use the phrase "determined in a manner that takes into account the volume or value of referrals or other business generated between the parties," the Post-Interoperability Exception uses the phrase "determined in a manner that is directly related to the volume or value of referrals or other business generated between the parties." The Post Interoperability Exception then goes on to

state that a "determination is deemed not to be directly related to the volume or value of referrals or other business generated between the parties" if:

- "[t]he determination is based on the total number of prescriptions written by the recipient,"
- "[t]he determination is based on the size of the recipient's medical practice (for example, total patients, total patient encounters, or relative value units),"
- "[t]he determination is based on the total number of hours that the recipient practices medicine,"
- "the determination is based on the recipient's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor),"
- "[t]he determination is based on whether the physician is a member of the hospital's medical staff, if the donor is a hospital," or
- "[t]he determination is made in any reasonable and verifiable manner that is not directly related to the volume or value of referrals or other business generated between the parties."

B. Comments

VHA strongly recommends that CMS adopt a single standard for purposes of all three proposed Exceptions. The term "takes into account" is vague, ambiguous and has no commonly understood meaning, and the term "directly related to" falls into the same category. Instead of requiring providers and practitioners to attempt to divine the meaning of and apply both of these standards, CMS should select one and incorporate it into each Exception.

Relatedly, whichever standard is adopted, CMS should clearly define it — with multiple examples of conduct that both meets and does not meet the standard — in each of the three Exceptions. As noted above, in the text of the Post-Interoperability Exception, CMS provides several helpful examples of conduct that meets the "directly related to" standard. In addition, in the preamble, CMS provides one example of conduct that meets and one example of conduct that does not meet the "takes into account" standard in the Electronic Prescribing Exception. However:

- in the text of the Electronic Prescribing Exception, CMS does not provide any examples of conduct that meets the "takes into account" standard or conduct that does not meet this standard;

- in the text of the Pre-Interoperability Exception, CMS does not provide any examples of conduct that meets the "takes into account" standard or conduct that does not meet this standard; and

- in the text of the Post-Interoperability Exception, CMS does not provide any examples of conduct that does not meet the "directly related to" standard.

The need for examples and "bright lines" is two-fold. First, as noted above, the terms "takes into account" and "directly related to" are not self-defining. Second, because the Stark law is, in essence, a strict liability statute, in the absence of bright lines — allowing providers and practitioners to be sure that their financial relationships do not preclude patient referrals — the three Exceptions simply will not be used, thereby undermining their principal policy objective (i.e, to promote the rapid and widespread adoption of electronic prescribing and EHR technology).

Finally, in addition to selecting a single standard and defining it clearly and with multiple examples (in each Exception), CMS should ensure that the definitions of the standard selected permit the dissemination of electronic prescribing and EHR technology under the broadest possible circumstances. By way of example only, a hospital should be able to use selection criteria such as (1) the size of the medical practice at issue (as the rapid and widespread adoption of electronic prescribing and EHR technology is more likely to be achieved efficiently and effectively through larger groups), (2) physician specialty, (3) the level of utilization of current hospital or other health care information technology systems, and/or (4) the level of participation in hospital and medical staff activities.

* * *

In closing, on behalf of VHA and its members, I would like to thank CMS for providing us this opportunity to comment on the Proposed Exceptions. Please feel free to contact me at (202) 354-2607 if you have any questions or if VHA can provide any assistance as you consider these issues.

Respectfully submitted,

Edward N. Goodman

Edward N. Goodman
Vice President, Public Policy
VHA Inc.

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SOUTH CAROLINA HOSPITAL ASSOCIATION
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December 8, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

Re: CMS-1303-P; Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements; Proposed Rule.

Dear Dr. McClellan:

On behalf of our 90+ member hospitals and health care systems, the South Carolina Hospital Association (SCHA) appreciates the opportunity to comment on the proposed rule regarding exceptions for certain electronic prescribing and electronic health records arrangements. We concur with the comments previously submitted by the American Hospital Association.

The proposed rule seeks to give hospitals more flexibility with protections from prosecution under the Stark law when they provide physicians on their medical staffs with certain IT items and services under three scenarios:

1. Provision of resources for e-prescribing;
2. Provision of electronic health record (EHR) software and directly-related training in advance of national standards for interoperability; and
3. Provision of EHR software and directly-related training after national standards for interoperability have been adopted and incorporated into a certification process.

The proposed rules define the protected arrangements, including those between hospitals and members of their medical staff who routinely furnish services at the hospital. Conditions include limitations on the covered technology, a requirement that the donated items are not "technically or functionally equivalent" to items the recipient already has, and documentation requirements. The exception also states that the donor must not consider the volume or value

of referrals or other business generated between the physician and the donor, and must comply with the anti-kickback statute.

Pre- and post-interoperability periods

The proposed rule outlines two distinct EHR exceptions – one in the pre-interoperability period and one post-interoperability. The demarcation between these periods would be the adoption of EHR certification criteria by the Secretary, including interoperability criteria. The exception would be slightly broader in the post-interoperability period.
While hospitals share the goal of achieving interoperability, tying the broader Stark exception to a certification process that does not yet exist will not provide the clarity or flexibility needed for hospitals to feel comfortable

Given the uncertainty surrounding certification, the SCHA urges CMS to adopt a single exception without the certification requirement, not two exceptions for the pre- and post-interoperability periods.

Defining "necessary"

The MMA limited the exception to "necessary" items or services, but we believe CMS has defined "necessary" too narrowly. Expressing concerns about increased risks of recipients intentionally divesting themselves of technology items or services they already have, CMS states explicitly that the exception would not cover the provision of items or services that are "technically or functionally equivalent" to those the recipient currently poses or has obtained. CMS, however, indicates that it does not interpret "necessary" to preclude upgrades that significantly enhance the functionality of the item or service. CMS offers no further guidance on the meaning of "technically or functionally equivalent" or what is meant by "significantly enhance the functionality" of the item or service. Rather the recipient would be required to "certify" that items and services to be donated are not equivalent. Additionally, the donor must not have actual knowledge of, and act in reckless disregard or deliberate ignorance of, the fact that the recipient possesses or has obtained such equivalent items or services.

Recipients are unlikely to possess the sophisticated level of understanding of capabilities and functionalities of available technology items and services that this standard seems to require. The burden and expense of making such determinations, therefore, is likely to fall primarily on hospitals and others who are donating the technology. Without clearer guidance on the terms used in the regulation and precisely how to make equivalency determinations, hospitals will not have confidence in the proposed exception. For example, if a physician already has a hand-held device that would be sufficient to run the requisite EHR software, but would require extensive and costly modifications to enable it to communicate with the hospital's existing information system, would a replacement be characterized as "technically or functionally equivalent?" CMS should offer guidance that enables any physician to make the required equivalency determination without needing to engage expensive technical and legal consultation services. In addition, CMS should facilitate sharing technical information about equivalency across donors and recipients so that they can take advantage of existing information and avoid duplicative efforts.
Covered technology

The proposed rule narrowly defines the covered technology as EHR software that does not include administrative functions but does include e-prescribing modules that conform to Medicare Part D standards just published. Directly-related training is the only permitted support under the proposed rule.

SCHA is concerned with the narrow definition of covered technology. The products on the market increasingly integrate administrative functions with the clinical EHR. Many situations require merging administrative and clinical data: clinical data must be accessed to support automatic prescription refill authority, clinical data must be aggregated for quality reporting, bills are derived from the clinical record, etc.

Furthermore, while software and directly-related training clearly are important to physician adoption of EHR, they are not sufficient. Physicians may not have the technical knowledge or resources to procure, implement and manage all of the necessary items. In addition, as hospitals expand their IT systems, they must incorporate communication and data transfer capability to physician offices into their IT infrastructures. In a wired health care system, physician access to hospital IT systems and communication between hospitals and physicians will be as necessary to providing high quality care as use of an operating room and recovery suite. Hospitals will need to maintain this IT infrastructure and protect its security and integrity. For these reasons, hospitals may want to provide other kinds of support to physicians to ensure that implementations are successful and information can be exchanged safely, such as:

- T1 lines or other enhanced broadband connectivity, including those needed to support transfer of medical images and EKGs, particularly in rural areas. This may include related software and hardware, such as routers to speed download times.
- Secure connections and messaging. Without ensuring that physician office systems have adequate security protocols and secure messaging, hospitals could put their own IT systems at risk when they connect.
- Ongoing maintenance and support. If physician office systems are not upgraded and maintained in the same manner as hospital systems, the ability to share clinical data to improve care will not be sustained.
- Interfaces. If a physician office already has an EHR that is not easily interoperable with the hospital system, the hospital may wish to provide the programming and software needed to interface the two systems. This kind of support clearly promotes interoperability, but is not allowed under the proposed exception.

Given the nature of technology, many of these items are multifunctional. For example, physicians could use the connectivity that allows them to exchange data with the hospital to also access general internet sites. However, it is not practical, and does not promote interoperability, if physician offices must use a connection only to exchange data with a given hospital. We urge CMS to define multifunctional connectivity, including related software and hardware, as covered technology. Incremental approaches may be possible, where the technology necessary for connectivity is covered, while any costs associated with additional uses are borne by the physician.

Permissible donors and selection of recipients

Permissible donors are those in the protected arrangement between a hospital and physicians who are members of the medical staff that routinely furnish services at the hospital. However, the growth of hospitalists and intensivists means that many physicians are admitting patients to the hospital, but not furnishing services in the hospital. In these cases, the need for clinical information exchange is even greater, since the hospital-based physician in charge of the patient will not have the same knowledge as the admitting physician. Similarly, many physicians refer patients to hospitals for outpatient care, and would benefit from having electronic access to test results that they can incorporate into their own EHRs. Therefore, the SCHA urges CMS to change the criteria to physicians on the medical staff whose patients frequently receive inpatient and outpatient care at the hospital.

While allowing hospitals to donate covered technology to members of the medical staff, the proposed rule states that IT cannot be used to entice physicians away from other hospitals. While the SCHA understands the pro-competitive intent of this restriction, it puts hospitals in a difficult spot. Will offering covered technology to all members of the medical staff – including new members – be construed as an attempt to entice physicians away from other hospitals? If so, how can they ensure all physicians are connected? The SCHA urges CMS to drop this provision to allow hospitals to work with new members of their medical staff, without being seen as trying to entice physicians from other hospitals.

The kinds of criteria that hospitals might want to use, and which would need protection, include:

- Participation in hospital quality improvement activities;
- Participation in medical staff meetings and activities;
- Specialty (the need to exchange data is often greatest for internal medicine or general practice);
- Department (IT systems are often rolled out by department);
- Readiness to use health IT;
- Consistent use of hospital-based IT systems, such as order-entry functions;
- Acting as a physician champion of hospital-based IT systems;
- Willingness to serve as a trainer for other physicians;
- Size of medical practice (it can be more efficient and effective to work with larger practices, which are often more ready to adopt IT); or
- Willingness to contribute some resources to the IT project

Cap on value

CMS suggests that it would be "appropriate to limit the aggregate value" of the technology a donor could provide to a recipient under the exception, believing that such a limit would minimize the potential for fraud and abuse. The SCHA believes that current imposition of any cap on the value of donated technology is, at best, premature and may unnecessarily and inappropriately inhibit wide-spread adoption. Hospitals' available financial resources necessarily will limit their ability to donate technology and related services to physicians and we are unlikely to see an explosion of hospital purchases of expensive and unnecessary technology as a result of the creation of an EHR-related Stark exception.

Other conditions

The SCHA applauds CMS for including the condition that physicians cannot make receipt of technology a condition of doing business with a hospital. Not all hospitals are in a position to assist physicians in adopting EHRs and they should not be coerced into doing so.

The proposed rule also requires that covered arrangements not violate the anti-kickback law. Given this condition, the impact of any exception to the Stark regulations on physician use of IT will be minimal if there is not a parallel safe harbor to the anti-kickback regulations. While the anti-kickback statute requires intent of wrong-doing, and is therefore more difficult to violate, the severity of the criminal penalties limit hospitals' willingness to act without specific guidance. The SCHA is also submitting comments to the OIG on their proposed rule.

Thank you again for the opportunity to comment on this proposed rule.

Sincerely,

Trudy Solomon

Trudy Solomon, VP

cc: SCHA Member Hospitals

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DEC 12 2005

athenahealth

December 9, 2005

BY EXPRESS MAIL

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1303-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Medicare Program: Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements
File Code: CMS-1303-P

To Whom It May Concern:

I am writing on behalf of athenahealth, Inc. ("Athena") to comment on the proposed rule creating exceptions to the physician self-referral prohibition in section 1877 of the Social Security Act (the "Act") for certain electronic prescribing and electronic health records arrangements (the "Proposed Rule").

We applaud the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) for seeking to remove financial and legal barriers to the adoption of interoperable electronic health records. In our view, the Proposed Rule is an important first step in addressing these barriers. However, as discussed further below, we believe the Proposed Rule requires modification to more clearly protect the full range of information technology solutions available in the marketplace.

Accordingly, we recommend a number of changes to the Proposed Rule. Most importantly, we offer a revised definition of Covered Technology that expressly protects integrated information technology solutions that combine software functionality, services, and transaction process guidance.

Executive Summary

We have organized our comments into several sections.

- First, we provide background information on Athena and its information technology products, services and business model. This information provides an

athenahealth, Inc. 311 Arsenal Street Watertown, MA 02472 www.athenahealth.com

The integrated solution therefore offers tremendous advantages, considering that the vast majority of physician practices are not configured to provide these services themselves or to source them elsewhere. Not only is a practical result – the result that most physician practices seek – provided by a single source, but the integrated solution also contributes to a more reliable and accurate result by centralizing and standardizing the services that surround technology. For example, an EHR that is bundled with a PMIS to use a shared patient demographic data base avoids the potential for error (and for the attendant possible bad medical results) that would be involved in a transfer of demographic data between the systems, either by hand or even on a batched electronic basis.

B. Comments on "Background" Section of Proposed Rule

In this section, we offer our views on the principles that should guide the Proposed Rule and the exceptions it creates.

We agree wholeheartedly with the comments in the Background section of the Proposed Rule concerning the benefits of information technology and the need for HHS to encourage its adoption. Moreover, we concur with the belief expressed therein that "interoperable electronic health records systems...can mitigate many of [HHS'] concerns regarding the potential anti-competitive effects of stand-alone electronic health records systems" (70 Fed. Reg. at 59183), as well as the risk of program abuse.

We urge HHS to expressly articulate in its final regulations on this matter certain overriding principles that should guide the creation and interpretation of its new exceptions and safe harbors. We recommend the adoption of five key principles, as follows:

- The Proposed Rule should not discourage physicians from selecting the technology solution that best fit their needs, provided those solutions are consistent with the federal government's objectives of promoting the use of interoperable health information technology. The federal government should not take action that favors one solution over another, but rather should allow the marketplace to work unfettered by regulatory bias or preference. Specifically, the Proposed Rule must expressly protect integrated technology solutions such as Athena's, on no less favorable terms than any other solution that meets HHS' interoperability test.

- The Proposed Rule should not discourage the adoption of comprehensive clinical functionality. While the federal government may adopt standards for certain clinical applications faster than for others (e.g., electronic prescribing), it should encourage the adoption of comprehensive electronic health record (EHR) applications, functionality and enabling services as soon as possible. In fact, comprehensive solutions, rather than stand-alone software applications or hardware, are far more likely to be adopted successfully because they deliver a greater return on investment to physician practices.

- The Proposed Rule should protect integrated technology products and services (e.g., those that include both administrative and clinical functionality), provided such products and services enable, as *a core component* of their functionality, the creation and maintenance of interoperable health records and data exchange capability, and the execution of electronic transactions. As described above, integrated products and services such as Athena's are proving attractive to large segments of the physician community (particularly smaller and mid-sized physician practices, and those in rural and other underserved areas) because they offer a complete solution to such practices' technology needs.

- The Proposed Rule should promote not only the adoption of interoperable electronic health record systems, but also the use of those systems. Indeed, the objectives of HHS will not be served if theoretically interoperable EHRs are not in fact used. The adoption of interoperable electronic health record systems, consisting of hardware, software, information technology support, connectivity services, training, and related transaction support services, will result in the creation and maintenance of EHRs and the exchange of clinical data among providers, suppliers, payers and others in an accurate, secure, and effective manner.

- The Proposed Rule should protect qualified technology products and services, whether directly installed at and operated by physician practices, or web-based and serviced by third party companies. The focus of this regulation should be on results rather than methods. As demonstrated by the description of Athena's product and service offering above, a third party company can perform invaluable integrated technology services, in such areas as interface development, data conversion, and administration of data exchange, that actually *enable interoperability* among physician practices and their trading partners.

The principles set forth above share a common theme: the Proposed Rule must protect technology solutions – including integrated software and services solutions – that promise to deliver the policy outcome desired by HHS and many others, namely truly interoperating EHR systems. We detect a concern in the Proposed Rule that the only way to address fraud and abuse risks is to narrow the definition of Covered Technology, thereby reducing the remuneration provided by technology donors to physicians. We maintain that this approach threatens to frustrate the very policy objective underlying the promulgation of the Proposed Rule.

As outlined below, we believe that CMS can address its fraud and abuse concerns by limiting the value of donated Covered Technology during the pre-interoperability period and requiring physicians to bear some of its cost, and by carefully establishing Product Certification Standards thereafter to only protect truly interoperating systems.

C. Comments on Specific Provisions of Proposed Rule

We set forth below our comments on specific provisions of the Proposed Rule. We have also attached a chart that summarizes our comments along side the categories used by

HHS in its outline of the Proposed Rule. As described in that chart, our comments pertain to each of the exceptions proposed by CMS, i.e., the electronic prescribing exception, the pre-interoperability electronic health records exception, and the post-interoperability electronic health records exception.

1. Covered Technology

   Problem with current draft: The definition of protected Covered Technology in both the proposed electronic prescribing exception and safe harbor, and the electronic health records exceptions and safe harbors, is too narrow. The Proposed Rule protects the provision of items and services that are "necessary and used solely" to transmit and receive electronic prescribing drug information, or receive, transmit, and maintain electronic health records, respectively. This definition could be interpreted to exclude integrated, multi-function technology products and services of the type that Athena offers – even though they accomplish electronic prescribing and electronic health record data exchange.

   Further, the definition of Covered Technology in the electronic health records exception during the pre-interoperability period (i.e., until Product Certification Standards are adopted by the Secretary of Health and Human Services (the "Secretary")) is limited to "software and directly related training services." This definition could also be viewed as excluding integrated software and services solutions.

   Moreover, the proposed definition of protected Covered Technology in the post-interoperability period is limited to "certified EHR software and directly related training services." Protected Covered Technology cannot include "any billing, scheduling, or other similar general office management or administrative software or services, nor ... staffing of physician offices." Although the commentary to the Proposed Rule invites comments on this provision and suggests an openness to the inclusion of administrative software or services if EHR software is a "core function of the donated technology" (see 70 Fed. Reg. at 59190), even this flexibility might not cover integrated products and services.

   Since the Stark Law and Anti-Kickback Statute have such a broad reach and carry such serious penalties, the failure to include an express exception for integrated technology and services in the Proposed Rule may lead providers and others in the health care industry to conclude that they are not protected.

   Accordingly, physician practices that use or wish to use integrated technology solutions may not be able to obtain assistance from potential donors of electronic technology, even though it is their system of choice.

   Proposed solution: We suggest that the Proposed Rule be modified to correct the problems identified above as follows:

   - The definition of protected Covered Technology should:

- Include "qualified health information technology" meaning "hardware, software (whether installed locally or web-based), license, right, intellectual property, equipment, or other information technology, or related services, used in connection with the creation and maintenance of interoperable health records and data exchange capability, and the execution of electronic health transactions including, without limitation, electronic prescribing transactions."

- Define "related services" as "support, connectivity, training and other items and services."

- Expressly protect "integrated or bundled products and services (including physician office administrative functionality) that enable, as a core component of their functionality, the creation and maintenance of interoperable health records and data exchange capability and the execution of electronic health transactions."

- The Proposed Rule should not differentiate the components of protected Covered Technology during the pre-interoperability and post-interoperability periods. Instead, until there are Product Certification Standards in place, physicians should be able to receive Covered Technology (as defined above) from donors, subject to a dollar cap on the value of protected Covered Technology.

2. Standards with Which Covered Technology Must Comply

Problem with current draft: The Proposed Rule calls for Covered Technology to meet the Product Certification Standards for electronic health records adopted by the Secretary. Athena is concerned that these standards may not expressly encompass integrated technology solutions that go beyond traditional licensed EHR software.

Proposed solution: The Proposed Rule should require that the Product Certification Standards for electronic health records expressly cover any technology or technology bundled service that enables, as a core component of its functionality, the creation and maintenance of interoperable health records and data exchange capability, and the execution of electronic health transactions.

3. Permissible Donors

Problem with current draft: The Proposed Rule includes group practices in the category of permitted donors of Covered Technology. As such, the Proposed Rule could be interpreted to prohibit group practices from making Covered Technology available to its members without compliance with the new regulation. This confusion may have the unintended consequence of discouraging group practices from adopting Covered Technology.

Proposed solution: The Proposed Rule should expressly provide that group practices meeting the current Stark Law definition of bona fide group practices are not subject to the requirements of the new regulation with respect to any technology and service that they provide to practice members.

4. Value of Protected Technology

Problem with current draft: The Proposed Rule invites comment on "whether to limit the aggregate value of all items and services provided to a physician from a single donor." Further, the Proposed Rule suggests that the cap would be increased during the post-interoperability period.

While we understand the desire for some limit on donations of protected Covered Technology during the period before Product Certification Standards are adopted, we do not believe a cap is required in the post-interoperability period. Product Certification Standards will ensure that Covered Technology is interoperable and in doing so will define what is necessary for interoperation. The adoption of interoperating health record systems offers the best protection against the feared risks of program abuse (including the rewarding of referrals of Federal health care program business) because such systems enable physicians to transact business with any and all trading partners. Essentially, the ability of physicians using a technology to establish relationships, make referrals and to conduct transactions without constraint is the best guarantee that a donor of that technology will not have undue influence over medical choices or that physicians will not perceive themselves as beholden to or dependent on that donor.

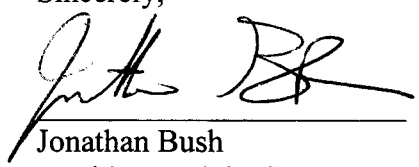
Proposed solution: To mitigate the potential risk of abuse prior to the adoption of Product Certification Standards, the Proposed Rule should cap the value of protected Covered Technology that can be donated by any one donor in any given calendar year at the lesser of (a) a specified percentage of the cost of such Covered Technology and (b) a fixed dollar amount per physician. At this time, we do not express an opinion on how to set the specified percentage and fixed dollar amount. Nonetheless, we believe the important point is that requiring a physician to bear some portion of the costs of the donated Covered Technology will ensure that the physician continues to act as a discriminating consumer of goods and services. This result will promote a more responsive and competitive technology vendor marketplace – which we welcome – as well as mitigate the risk that donors will offer physicians elaborate technology in the hope of inappropriately influencing referral relationships.

Following the adoption of such Product Certification Criteria, however, there should be no limit on the value of donations of Covered Technology, provided that aggregate donations do not exceed the fair market value of the Covered Technology and donors and recipients are in compliance with the other provisions in the Proposed Rule.

Lastly, the Proposed Rule should expressly provided that donated Covered Technology costs include both upfront costs (including implementation costs) and ongoing product and service costs.

We are prepared to submit additional information in support of our comments, and to answer any questions that may arise. We are also ready to meet with CMS officials to elaborate on any aspect of our comments. If you would like to contact us, please contact Christopher Nolin, Athena's General Counsel at 781-392-0256 or cnolin@athenahealth.com.

Sincerely,



Jonathan Bush
President and CEO

	MMA-Mandated Electronic Prescribing Exception/Safe Harbor	Pre-Interoperability electronic Health Records Exception/Safe Harbor	Post-Interoperability Electronic Health Records Exception/Safe Harbor	Athena Comments
Authority for Proposed Exception	Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003	•Section 1877(b)(4) of the Social Security Act •Section 1128B(b)(3)(E) of the Social Security Act	•Section 1877(b)(4) of the Social Security Act •Section 1128B(b)(3)(E) of the Social Security Act	

	MMA-Mandated Electronic Prescribing Exception/Safe Harbor	Pre-Interoperability electronic Health Records Exception/Safe Harbor	Post-Interoperability Electronic Health Records Exception/Safe Harbor	Athena Comments
Covered Technology	•Items and services that are necessary and used solely to transmit and receive electronic prescription drug information •Includes hardware, software, internet connectivity, and training and support services	•Software used solely for the transmission, receipt or maintenance of EHRs •Directly-related training services •Software must include an electronic prescribing component	•Certified EHR software •Directly-related training services •Software must include an electronic prescribing component •Could include billing and scheduling software, provided that the core function of the software is EHRs	•Should cover any technology or technology service that can deliver the desired outcome, i.e. adoption and use of interoperable health records and data exchange capability, including electronic prescribing. •Proposed Rule should expressly protect "qualified health information technology" meaning "hardware, software (whether installed locally or web-based), license, right, intellectual property, equipment or other information technology, or related services, used in connection with the creation and maintenance of interoperable health records and data exchange capability, and the execution of electronic health transactions including, without limitation, electronic prescribing transactions." •"Related services" should be defined as "support, connectivity, training and other items and services." •Proposed Rule should expressly protect "integrated or bundled products and services that enable, as a core component of their functionality, the creation and maintenance of interoperable health records and data exchange capability, and the execution of electronic health transactions including, without limitation, electronic prescribing transactions. •Proposed Rule should not differentiate the components of protected Covered Technology during the Pre-Interoperability and Post Interoperability periods. Until there are Product Certification standards, providers should be able to receive Covered Technology (as defined above) from donors, subject only to the specific dollar caps on the value of protected Covered Technology (see below).

	MMA-Mandated Electronic Prescribing Exception/Safe Harbor	Pre-Interoperability electronic Health Records Exception/Safe Harbor	Post-Interoperability Electronic Health Records Exception/Safe Harbor	Athena Comments
Standards with Which Donated Technology Must Comply	•Foundation standard for electronic prescribing as adopted by the HHS Secretary	•Electronic prescribing component must comply with foundation standards for electronic prescribing as adopted by the Secretary	•Product certification criteria adopted by the Secretary •Electronic prescribing component must comply with foundation standards for electronic prescribing as adopted by the Secretary, to the extent these standards are not fully incorporated into the product certification criteria	• Product certification standards for electronic health records adopted by the Secretary should expressly cover any technology or technology service that can deliver the designed outcome, i.e. the creation and maintenance of interoperable health records and data exchange capability, and the execution of electronic health transactions.
Permissible Donors	•As required by statute, hospitals (to members of their medical staffs), group practices (to physician members), prescription drug program (PDP) sponsors and Medicare Advantage (MA) organizations (to physicians, network pharmacists, and pharmacies, and to prescribing health care professionals)	•Hospitals to members of their medical staffs •Group practices to physician members •PDP sponsors •MA organizations	•Hospitals to members of their medical staffs •Group practices to physician members •PDP sponsors •MA organizations	• Proposed Rule should clarify that Group Practices meeting the current Stark Law definition should be free to adopt and disseminate information technology items and services to their physician members.
Selection of Recipients	•Donors may not take into account the volume or value of referrals from the recipient or other business between the parties	•Donors may not take into account the volume or value of referrals from the recipient or other business between the parties	•Donors may use criteria to select recipients that are *not directly related* to the volume or value of referrals or other business generated between the parties	

	MMA-Mandated Electronic Prescribing Exception/Safe Harbor	Pre-Interoperability electronic Health Records Exception/Safe Harbor	Post-Interoperability Electronic Health Records Exception/Safe Harbor	Athena Comments
Value of Protected Technology	•No specific dollar amount proposed for a cap on the value of protected technology	•No specific dollar amount proposed for a cap on the value of protected items and services	•No specific dollar amount proposed for a cap on the value of protected items and services •May be greater than the cap on pre-interoperability donations	•During the Pre-Interoperability period, propose a dollar cap equal to the lesser of (a) specified percentage of the cost of the protected Covered Technology, and (b) a fixed dollar amount per physician, from any one donor in any calendar year. •There should be no cap on the value of donated Covered Technology during the Post-Interoperability period (other than a limitation to the fair market value of such Covered Technology). •The dollar cap should expressly cover both upfront costs (including implementation services) and ongoing service costs.

Making a Difference in Healthcare™

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December 9, 2005

DEC 12 2005

The Honorable Mark McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Baltimore, Maryland 21244-1850

Dear Dr. McClellan:

IDX is pleased to submit our comments regarding the Centers for Medicare and Medicaid (CMS) Proposed Rule on providing Stark Regulation Exception for electronic prescription services (eRx) and Electronic Health Records (EHRs). We appreciate the efforts that you and your colleagues at the Office of the Inspector General have made in offering pragmatic regulations regarding the application of safe harbors for eRx and EHRs. The proposed Anti-Kickback Statute Exception, along with the proposed Safe Harbors for eRx and EHRs, are important regulatory tools that should be used cautiously in the absence of market forces that would otherwise provide the incentives to enable adoption of health information technology.

IDX believes that Safe Harbors for healthcare IT should be allowed only if the exemptions required the donating entities (e.g., hospitals) and receiving entities (e.g. physicians) to implement interoperability policies and standards that would not limit or restrict the exchange of patient health information with any other IT system necessary. These interoperability policies and standards would ensure portability of information to improve the quality, safety and efficiency of the patient's health management, and should be the foundation for any exemptions considered for eRx and EHRs.

As the Department's strategy changes from a reactive, late stage healthcare delivery model to a proactive, early health model that empowers consumers to manage their health, it is essential that the healthcare delivery infrastructure ensure the portability of a patient's health information. Portability provides patients the flexibility to choose services based on what providers offer, with competitiveness driven by differentiation of quality and cost of care. For physicians to be competitive in such a market-based healthcare delivery system, they must be empowered with the choice of IT systems that provide the best benefits to their patients, such as the ability to negotiate services contracts with additional or alternative providers.

The enabler for patient information portability is in ensuring interoperability amongst all IT systems in the range of care that the patient encounters, where interoperability is defined as the uniform and efficient movement of electronic healthcare data from one system to another, such that the clinical or operational purpose and meaning of the data is preserved and unaltered. Interoperability requirements have a technology component and a policy component.

IDX recognizes that interoperability technology, as expressed in the various standards and verified through product certification, will not guarantee that the interoperability required in the certified products will be deployed in a manner that ensures its intended use, and as a result the pre-interoperability and post-interoperability phases proposed by CMS and OIG will not achieve their intended effect. Therefore, IDX believes that interoperability policies must be used to drive the market to demand the technology component of interoperability of eRx and EHRs. With the exception of the Federal Government, no stakeholder with market power in the healthcare industry today has strong incentives to demand interoperability.

We believe that the healthcare industry will move with speed and creativity to achieve interoperability only if government financial and regulatory incentives are predicated upon the achievement of interoperability in actual care settings. As in any other industry, innovation and value in healthcare systems will be accelerated with robust competition. Interoperability is a precondition for robust competition. If government financial and regulatory incentives for healthcare IT adoption are introduced without strong policies to drive interoperability, current proprietary platforms will be extended into the marketplace and will stifle competition, innovation and value in healthcare IT systems.

Government mandated interoperability standards will always lag product and market innovations, which is why IDX believes that interoperability requirements must be driven by predicating the receipt of government financial and regulatory incentives on conditions that demand interoperability in practice. In our response, we have provided suggestions on how the Stark and Anti-kickback safe harbors can be structured to incentivize the market to drive rapid interoperability. IDX believes that interoperability does not need to be sacrificed to achieve widespread adoption of healthcare IT. Rather, with careful crafting of the safe harbors we can achieve widespread adoption of IT in an interoperable framework.

We look forward to working with the Department and our healthcare industry colleagues to make responsible changes to the Stark and Anti Kickback Act regulations that will advance HIT implementation in support of improved patient safety and healthcare quality. If you have any additional questions please contact me, at (802) 859-6506, tom_horton@idx.com.

Sincerely,

Thomas G. Horton
Sr. Vice President
Strategy and Business Development

IDX Response to HHS Proposed Regulations Providing Stark Exceptions and Anti Kick Back Act Safe Harbors for Electronic Prescribing and Electronic Health Records

December 12, 2005

Response Overview for OIG-405-P & CMS 1303-P

IDX is pleased to submit our comments regarding the Centers for Medicare and Medicaid CMS-1303-P and Office of the Inspector General (OIG) OIG-405-P Proposed Rules on Stark Regulation and Anti-Kickback Statute exceptions respectively for electronic prescription services (eRx) and Electronic Health Records (EHR). The proposed Stark Regulation Exception, along with the proposed Safe Harbors for eRx and EHR, are important regulatory tools that should be used cautiously in the absence of market forces that would otherwise provide the incentives to enable adoption of health information technology.

IDX believes that safe harbors for healthcare IT should be allowed only if the exemptions required the donating entities (e.g., hospitals) and receiving entities (e.g. physicians) to implement interoperability policies and standards that would not limit or restrict the exchange of patient health information with any other IT system necessary. These interoperability policies and standards would ensure portability of information to improve the quality, safety and efficiency of the patient's health management.

As the Department's strategy changes from a reactive, late stage healthcare delivery model to a proactive, early health model that enables higher quality and efficiency through consumer empowerment, it is essential that the healthcare delivery infrastructure ensure the portability of consumer health information. Portability provides patients the flexibility to choose and manage services based on what providers offer, with competitiveness driven by differentiation of quality and cost of care. For physicians to be competitive in such a market-based healthcare delivery system, they must be empowered with the choice of IT systems that provide the best benefits to their patients, such as the ability to negotiate services contracts with additional or alternative providers.

The enabler for portability is in ensuring interoperability amongst all IT systems in range of care that the patient encounters, where interoperability is defined as the uniform and efficient movement of electronic healthcare data from one system to another such that the clinical or operational purpose and meaning of the data is preserved and unaltered. Interoperability requirements have a technology component and a policy component. The technology component includes the data standards and integration profiles used to describe the structure, format and context of data being exchanged. The interoperability policy component provides the "rules of the road" as to what minimum types of data should be exchanged and the equity of availability of the information to all entities that require exchange capability within the range of care required by patient.

IDX recognizes that interoperability technology, as expressed in the various standards and verified through product certification, will not guarantee that the interoperability required in the certified products will be deployed in a manner that ensures its intended use, and as a result the pre-interoperability and post-interoperability phases proposed by CMS and OIG will not achieve their intended effect. Therefore, IDX believes that the interoperability policy component must be used to drive the market to demand the technology component of interoperability of eRx and EHR.

With the exception of the Federal Government, no stakeholder with market power in the healthcare industry today has strong incentives to demand interoperability.

IDX believes that the healthcare industry will move with speed and creativity to achieve interoperability only if government financial and regulatory incentives are predicated upon the achievement of interoperability in actual care settings. As in any other industry, innovation and value in healthcare systems will be accelerated with robust competition, and interoperability is a precondition for robust competition. If government financial and regulatory incentives for healthcare IT adoption are adopted without strong policies to drive interoperability, current proprietary platforms will be extended into the marketplace and will stifle competition, innovation and value in healthcare IT systems.

Government mandated interoperability standards will always lag product and market innovations, which is why IDX believes that interoperability requirements must be driven by predicating the receipt of government financial and regulatory incentives on conditions that demand interoperability in practice.

A summary of IDX's key recommendations regarding the proposed safe harbor regulations for eRx and EHR is given below, with detailed explanations in the appropriate comment sections that follow this summary.

A. IDX supports including EHR software, including any ancillary systems/components such as billing, scheduling and practice management in the definition of permitted donations so long as such software includes the required components of eRx software. IDX believes that providers should have maximum choice in determining the vendor applications that will be donated. Most vendor solutions are integrated EHR applications rather than stand-alone eRx modules. Expanding the definition of what may be donated will ensure that competition among vendors, as one of the preferred vendors for the donated solution will be maximized. This will help ensure that donors have many choices to drive the highest value solutions for donation to providers. The definition of an EHR must not explicitly or implicitly be only the EHR/clinical component or combined EHR/Practice management components. It must be any component of information management software used by a physician or medical group to operate the medical practice, e.g., Practice Management applications that have additional decision support capabilities that allow for more robust EHR (eligibility and claims data). Data from billing and scheduling systems is foundational data by which portability of patient information is established. Any incentive that does not recognize these existing capabilities as integral prerequisites to the exchange of clinical health information will be counterproductive.

B. IDX supports the NPRM requirement that donated software/systems cannot be used to replace existing capabilities already in place at the physician practice.
   - Donated software should be interoperable or made to be interoperable with existing provider IT systems (i.e., billing, scheduling, practice management systems), provided that those legacy IT system vendors can provide an upgrade path to standards-based (as required by CCHIT or HITSP) interoperability requirements.
   - Donation can include the integration services necessary to ensure interoperability with other IT systems deemed necessary by the physician.

- Donating software should be seen as providing extensibility to existing IT capabilities already in place in the physician practice.
- In order to prevent the delay of the implementation of healthcare IT by providers in anticipation of future donated healthcare IT, providers who have implemented technically or functionally equivalent software must be assured that their previously implemented equivalent systems are entitled to reimbursement by the donor in an amount equal to the lesser of the fair market value of the donated technology or the donated value cap. In addition, the donor must assure providers entitled to the donation that any previously purchased technology that is equivalent to donated technology will be integrated into the donor technology system so long as the previously purchased equivalent technology adheres to then current or anticipated federally mandated standards.

C. IDX supports capping the value of the donated eRx and EHR software donating proprietary solutions lock in incumbent vendors and provider referral networks. Therefore, both vendors and donors who benefit from locking in proprietary platforms and referral networks will subsidize incumbent proprietary platforms. The cost of interoperability will be borne by someone. IDX believes that the best way to protect against the lack of innovation and competition that will result from the lock in of incumbent vendors and provider referral networks is to ensure that there is a level playing field in the competition for the purchase of software that will comprise the donated technology. The way to ensure this is to cap donated software at no more than a predetermined dollar amount. Up to that dollar amount could be used for either the purchase of donated software or for any other software equivalent to the donated software, which could be shown to have a path toward integration with the donated software (without restriction by the donated software vendor) within a reasonable period. In order to determine the value of the cap, determine the average cost of the software system/module to a dollar value per physician, with value to be adjustable given factors such as inflation, the prevalence of accepted standards or certification requirements that typically lead to increased capability/content. Fair market value for eRx, EHR and related functionality such as scheduling and billing should be used in calculating the cap. The cap amount would be framed as a not to exceed contribution level towards the purchase eRx or EHR software similar to a coupon.

D. There should be no less than three EHR solutions from competing vendors offered by sponsoring donating entities, and an open RFP process for the selection of EHR, submitted to all applicable certified EHR as listed by CCHIT.

E. IDX supports interoperability requirements that place emphasis on interoperability policies than ensure portability of information between the donating entity and recipient, including other IT systems the recipient specifies in order to provide competitive services to their patients.
   - The donating entity must demonstrate interoperability policies that do not limit or restrict the use of the donated health information technology and related services in conjunction with other health information technology and related services requested or required by the recipient.
   - The donated software must meet current and anticipated interoperability requirements established for certified EHR set forth by HHS.

- The patient information provided to donate EHR must provide the same level of information interoperability (as defined CITL's four levels of interoperability, Walker, Pan, et al, Health Affairs, January 19, 2005, pg. W5-11) as EHR used by the donating entities physicians.

F. IDX supports exemptions based on donating entities participation in a recognized health information exchange (HIEs) operated by a neutral third party that has an appropriate governance structure, including policies and standards that require interoperability of patient information amongst all members of the exchange. IDX notes that Senate Bill S1418 includes language regarding grant requirements recognizing the value of community-wide HIEs in its grant qualification criteria.

G. Practices that have already implemented EHR functionality equivalent to that offered by the donating entity that meets HHS-mandated interoperability requirements should be compensated on a pro rata basis for the applications that the practices have already put in place.

H. IDX supports a provision that requires donating entities to provide data-migration services if a physician chooses to leave and purchase their own EHR, eliminating the most restrictive lock-in restriction. This requirement will become less of an issue as vendors implement standards-based interoperability solutions.

Detailed Response

Note:

- Due to the extensive overlap between the CMS and OIG proposed rules, we have consolidated the questions and responses for each proposed rule into a single response.
- Each numbered question includes a specific reference to the page and column of the NPRM as published in The Federal Register, Vol. 70, No. 195, Tuesday, October 11, 2005, as well as CMS reference section as appropriate

1. CMS and OIG ask for comment on the definition of "necessary" nonmonetary remuneration. (Pg. 59018, col. 1) (Electronic Prescribing Exception: 411.357v)

IDX appreciates the opportunity to comment on the issue of necessary nonmonetary remuneration. We are concerned that the distinctions drawn between software and hardware effectively do not include hardware in the EHR safe harbor, but do include it in the eRx safe harbor. We understand the legal challenges outlined by the provisions in the Medicare Modernization Act; however, the distinction does not seem practical, especially in a context where the EHR must include eRx to qualify for safe harbor.

With respect to connectivity services, drawing the distinction on donated versus purchased connectivity and internet services is difficult to parse out, as providers would be forced to identify which instances of internet usage where strictly for eRx, as opposed to other services. Practices need guidance on connectivity and installation requirements as much as on hardware or software. IDX suggests that connectivity and installation assistance should be a defined benefit of the

agreement on the safe harbor as opposed to a defined contribution, and recipients should be encouraged to select the 'wireless, broadband' access that best meets the provider's business needs.

Additionally, IDX suggests that the scope of 'Support Services', Training, and 'Other Items and Services' should be a defined contribution not to exceed 365 person-days and that the Department provide guidance on the nature of appropriate information technology support services (e.g. help desk) and define appropriate 'other items and services'.

2. CMS and OIG ask for comment on the issue of certification process for nonmonetary remuneration and whether a recipient should be required to submit a written statement on owned or donated services. (Pg. 59018, col. 2) (Electronic Prescribing Exception: 411.357v)

IDX supports the process of provider self-certification as to the lack of technical or functional equivalence contemplated in the proposed rules. However, to avoid a "chilling" effect on the deployment of both eRx (eRx) and Electronic Health Record (EHR) as providers may wait to adopt technology until a donation is provided, IDX believes that it is essential to provide that donors must reimburse providers who have already implemented technically or functionally equivalent solutions at a rate equivalent to the value of the lesser of the value cap or the donated technology.

IDX also suggests referencing 'prescribing healthcare professionals' and 'providers who are authorized to prescribe under applicable State licensing laws in lieu of singular references to 'Used solely" by a physician, to show clearly and deliberately the fairness of the proposed rule and the intent to include Nurse Practitioners and Midwives in the Stark Regulation Exception for electronic prescription services (eRx) and Electronic Health Records (EHR).

3. CMS and OIG ask respondents to comment on the proposed safe harbor for the donation of limited hardware, OS software, and connectivity services. (Pg. 59019, col. 1) (Electronic Prescribing Exception: 411.357v)

The proposal raises an excellent question on donation of hardware, Operating System (OS) software, connectivity services, etc. Like HHS, IDX is supportive of efforts to achieve greater levels of quality performance, and patient safety. More specifically, in order to achieve patient safety, quality performance, and efficiency goals dependent on the adoption of health information technology, it is essential to permit the optimum use of that technology. While donations for software and services improve access to the systems, success is dependent on having the right enabling infrastructure, including hardware, OS software, and connectivity. These elements, even in Application Service Provider (ASP) models, contribute significantly to total cost of ownership. For this reason, IDX recommends that the safe harbor be extended to cover these elements, provided that these elements are combined in a single transaction with the donation of the other safe harbor elements of eRx and EHR and where equivalent functionality does not already exist.

IDX also suggests the Department consider offering guidance on the term 'substantial'.

4. CMS and OIG ask respondents to comment on the standards that should appear in an additional safe harbor for multi-functional hardware, to include methodologies for

quantifying or ensuring that substantial use of hardware and connectivity services is for eRx. (Pg. 59019, col. 1) (Electronic Prescribing Exception: 411.357v)

IDX interprets that standards used in this context relate to the assessment criteria necessary to judge whether multi-functional hardware, operating system software or connectivity services meet the substantial use criteria associated with the donated eRx or EHR software. IDX suggests that four standards/criteria should be considered. First, the donating entity and recipient certify that the multi-functional hardware, operating system software and related connectivity services are essential for the purpose of the eRx or EHR. Second, the multi-functional hardware, operating system software and related connectivity services should be subject to a value cap at no more than a predetermined dollar amount, with fair market value being the maximum and recipient practice size also factored in. Third, the multi-functional hardware, operating system software and related connectivity services being offered should be consistent with the minimum system configuration and operating requirements required by the donated software. Fourth, EHR software should meet the industry required certification requirements as outlined by the CCHIT or other government-mandated certification.

5. CMS and OIG ask respondents to comment on the nature and amount of a cap on donated multi-functional hardware and connectivity services. (Pg. 59019, col. 1) (Electronic Prescribing Exception: 411.357v)

IDX generally supports the Department's view of providing caps as a safeguard against fraud and abuse. The practical concern is in establishing the value of the donated multi-functional hardware and connectivity services. IDX suggests that donated multi-functional hardware and connectivity be capped based on fair market value, since there is transparent pricing for these types of goods in the marketplace today. Another suggestion is to treat the cap for multi-functional hardware and connectivity services as a not-to-exceed value (like a coupon), where OIG can recognize a base amount for a recognized fair market value, and the recipient can choose to pay the additional cost for hardware or connectivity services above and beyond what is recognized as an acceptable base amount. The way to ensure this is to cap donated software at no more than a predetermined dollar amount. Up to that dollar amount could be used for either the purchase of donated software or for any other software equivalent to the donated software, which could be shown to have a path toward integration with the donated software (without restriction by the donated software vendor) within a reasonable period. In order to determine the value of the cap, the average cost of the software system/module should be determined per physician. The value must be adjusted to factors such as inflation, the prevalence of accepted standards or certification requirements that typically lead to increased capability/content.

IDX also recommends that the donating entity be required to offer hardware, software and connectivity solutions from a minimum of three vendors for the recipient to select, and require that these solutions be offered via a transparent RFP process. This multi-vendor, open RFP process ensures that competitive market pricing is provided; it allows the recipient to participate in the selection process to ensure that services meet the needs of their clinical practice as well as provides a safeguard against lock-in by the donating entity.

6. CMS and OIG ask respondents to comment on whether a safe harbor should be extended to items and services provided to other individuals or entities of a hospital (in addition to hospital physicians). (Pg. 59019, col. 2) (Electronic Prescribing Exception: 411.357v)

IDX encourages the Department to consider extending safe harbor to items and services provided to individuals or entities of a hospital, as well as other provider organizations, including connectivity services such as may be provided by Health Information Exchanges (HIEs) or through direct collaboration of provider organizations.

IDX also suggests referencing 'prescribing healthcare professionals' and 'providers who are authorized to prescribe under applicable State licensing laws in lieu of singular references to 'physician'. This will show clearly and deliberately the fairness of the proposed regulation and the intent to include Nurse Practitioners and Midwives in the Stark Regulation Exception for electronic prescription services (eRx) and Electronic Health Records (EHR).

7. CMS and OIG request comment on what other categories of donors and recipients should be covered besides PDP Sponsors and MA Organizations/ Pharmacies, Pharmacists, and Prescribing Healthcare Professionals relative to eRx. (Pg. 59019, col. 1) (Electronic Prescribing Exception: 411.357v)

IDX encourages the Department to broaden the list of recipients to be consistent with its usual broad view of healthcare delivery by using the generally accepted term within the Department "prescribing healthcare professionals." Other recipients should include secondary and tertiary care facilities, such as a skilled nursing, long term care facilities and ambulatory surgical centers.

As for the list of donors, IDX encourages the Department to consider including Pharmaceutical Manufacturers, medical device manufacturers and Integrated Delivery Networks, provided that these entities are affiliated with neutral third party health information exchanges (HIEs) and that the donation in question will be utilized in conjunction with the HIE in which the donor is engaged.

The development and deployment of HIEs is a public policy priority articulated by both the President and Congress. Including HIEs as appropriate donors for purposes of safe harbor could incent physician participation due the neutral governance and interoperability enforcement provided by the HIEs. Given that physicians typically have privileges at multiple hospitals, HIEs provide a natural infrastructure for interconnecting multiple competing entities with recipients. HIEs could also provide centralized purchasing and administration of commodity services such as connectivity and training services for recipients.

In the eHealth Initiative Annual Survey of State, Regional and Community-Based Health Information Exchange Initiatives and Organizations, September 2005, of the 109 HIEs qualified in the survey, 25 HIEs are already fully operational, with another 40 in the implementation stages. OIG could review the governance models of these HIEs for recommended regulations that mitigate the risk of fraud and abuse. Coupling HIEs AKS protection with the existing Stark exemption for Community Wide Health Information Systems would provide effective healthcare IT adoption incentives based on HIE interoperability policies.

Providing anti-kickback protection for groups like pharmaceutical companies that choose to invest in multi-stakeholder entities such as HIEs would allow the private sector to invest in creating community-wide health information infrastructure without concern for violating anti-kickback statutes. OIG should consider the governance, interoperability policy and technology guidelines put forth by eHI as a model for providing HIEs with the governance, policy and operating constructs that protect against fraud and abuse, while allowing donations from a broader group of donors that otherwise would not consider donating software, hardware or recognized services.

8. CMS and OIG ask respondents to comment on whether the safe harbor should extend to non-drug prescriptions. (Pg. 59020, col. 1) (Electronic Prescribing Exception: 411.357v)

In order to encourage provider utilization of eRx technology to increase safety, cost-effective practice, and efficiency, the Office of the Inspector General should support the use of eRx technology for all the functions currently accomplished through writing prescriptions. This includes prescribing imaging examinations, medical supplies (insulin syringes) and durable medical equipment (wheelchairs).

9. CMS and OIG ask respondents to comment on their proposed definition of Interoperable (pg. 59020, col. 2; pg. 59021, col. 3; pg. 59023, col.2) (Electronic Prescribing Exception: 411.357v, Pre-Interoperability Electronic Health Records Exception: Electronic 411.357w)

There are several definitions of interoperability. IDX notes the extensive definition of the levels of interoperability outlined by Walker, Pan, et al, of CITL Health Affairs, January 19, 2005, pg. W5-11). This definition recognizes the differential value of interoperability between sending a fax with blood pressures, versus sending a structured document with blood pressure values that can be "consumed" by a EHR application to aid in the workflow and decision support processing by the clinician. These different levels of interoperability must not be used by donating entities to differentiate, limit or restrict services between recipients or other entities that provide patient care via exchange of health information.

IDX defines interoperability as the uniform and efficient movement of electronic healthcare data from one system to another such that the clinical or operational purpose and meaning of the data is preserved and unaltered. Interoperability requirements have a technology component and a policy component. The technology component includes the data standards and integration profiles used to describe the structure, format and context of data being exchanged. The interoperability policy component provides the "rules of the road" as to what minimum types of data should be exchanged and the equity of availability of the information to all entities that require exchange capability within the affected healthcare market.

IDX believes that the interoperability policy component must be used to drive the market to demand the technology component of interoperability for eRx and EHR. With the exception of the Government, no stakeholder with market power in the healthcare industry today has both the strong incentives as well as the capacity to demand interoperability. IDX believes that the healthcare industry will move with speed and creativity to achieve interoperability only if government financial and regulatory incentives are predicated upon the achievement of interoperability in actual care settings.

Given the early stage of development of interoperability technology, the pre and post interoperability phases for EHR as envisioned in the NPRM should be differentiated by more strict interoperability policies that mandate portability and access to health information by donating entities to the recipient and other health IT systems designated by the recipient. IDX emphasizes that EHR certification does not address interoperability policies that donating entities must follow to ensure that interoperability capabilities of the certified EHR are deployed, and there are countless examples today where entities utilize open, non-proprietary standards, but administer information exchange via proprietary policies.

IDX is concerned with the statement in the NPRM (Federal Register Vol. 70, No.195, Oct. 11, 2005, page 59023, column one) that reads: "Moreover, hospitals, group practices, PDP sponsors, and MA organizations are potentially in a better position to promote widespread use of electronic health records technology that has the greatest degree of openness and interoperability." In practice the amount of fragmentation in our marketplace today is due to these and other entities that view patient information as proprietary, and access to these information silos serve as a means of locking in physicians and patients as related to their selection and delivery of the EHR and related current and future services, such as Patient Health Records. To suggest the contrary would not explain the reluctance of these and similar entities from forming health information exchanges. In the context of comparing these entities with ancillary services such as laboratories relative to embracing portability of patient information wherever and whenever providers that are delivering care need it, all are equally guilty.

IDX recommends the following interoperability policies be considered given the current state of interoperability technology with respect to supporting portability of patient information exchange.

1. Donated software must meet current and anticipated interoperability requirements established for certified EHR by HHS.
2. The donating entity must not limit or restrict the use of the donated health information technology and related services in conjunction with other health information technology and related services requested/required by the recipient. This includes existing health information technology systems in place in the recipient's office, such as billing and scheduling systems.
3. The patient information provided to the donated EHR must provide the same level of information interoperability (as defined by CITL levels of interoperability, Walker, Pan, et al, Health Affairs, January 19, 2005, pg. W5-11) as EHR used by the donating entities physicians.
4. The safe harbor should provide special recognition for exemptions based on the donating entity's participation in a recognized health information exchange, operated by a neutral third party that includes policies and standards that require interoperability of patient information amongst all members of the exchange (see Senate Bill S1418 language regarding grant requirements favoring health information exchanges.)
5. Practices that have already implemented equivalent EHR functionality to that offered by the donating entity should be both interoperable with the entity sponsored solution or interoperable with recognized government interoperability requirements and should be compensated on a pro rata basis for the comparable applications that the practices have already put in place.
6. Donating entities should be required to provide data-migration services if a recipient later chooses to purchase his/her own EHR. This eliminates the greatest potential lock-in

restriction for the donating entity. This financial requirement to the donor is reasonable because it becomes less of an issue as vendors implement standards-based interoperability technology.

IDX would like to provide its perspective on the state of interoperability standards given the comments in the NPRM (pg. 59021, Col. 3), "Currently, uniform interoperability standards for electronic health records and certification requirements to ensure interoperability do not exist." IDX notes that interoperability is a matter of degree and that requirements will increase as the build-out of the National Health Information Infrastructure occurs, making it difficult to establish a threshold between pre-interoperability and post-interoperability given the "moving target" of incremental enhancements. More importantly, EHR or eRx certified to meet interoperability requirements does not imply that donating entities or recipients will deploy them to meet their intended use. Only interoperability policies will ensure that the portability of patient information between entities will occur. While in theory any entity can create and implement policies that promote complete portability of patient information, IDX believes that only a neutral third party, such as an HIE with the appropriate governance and operating policies can ensure such portability is maintained by all the entities that exchange health information.

The eHealth Initiative Annual Survey of State, Regional and Community-Based Health Information Exchange Initiatives and Organizations, September 2005 cites several interoperability examples that are in place or planned by the HIEs surveyed. Note that it is through policies implemented by the HIEs that ensured that the portability of health information was provided among non-certified products and without the wide use of healthcare standards. These HIEs are exchanging medical summaries and medication lists TODAY!

IDX recognizes that the uniform use of standards applied to solve explicit interoperability transactions and clinical use-cases will accelerate interoperability adoption through requirements that can be certified in EHR products. At the February 2005 Health Information Management Systems and Society (HIMSS) / Integrating the Healthcare Enterprise (IHE) Interoperability Showcase more than 12 EHR and IT infrastructure vendors demonstrated the ability to exchange lab results, medical summaries between ambulatory and acute care settings in a health information exchange. The IHE showcase included a demonstration given to Dr. David Brailer, showing the portability of his "care record" as it moved from an ambulatory clinic, to a cardiologist, and on to a hospital. The interoperability demonstrated to Dr. Brailer by these competing vendors used existing standards that were implemented uniformly, which is referred to as an IHE integration profile. Going forward IDX anticipates CCHIT and the Health Information Standards Technology Panel (HITSP) to establish these profiles at a national level to solve the most critical interoperability issues, but interoperability policies must also be in place to enforce their implementation by donating entities and recipients.

10. CMS and OIG ask respondents to comment on the cap level for donated EHR that would protect against fraud and abuse and whether an initial cap and subsequent caps should be used as part of the formula. (Pg. 59022, col. 3) (Electronic Prescribing Exception: 411.357v)

IDX generally supports the Department's view of providing caps as a safeguard against fraud and abuse. The practical concern is in establishing the value of the donated EHR software is in establishing its fair market value relative to various functional components that can make up an

EHR system. EHR should be viewed to include not only its typical clinical point of care and decision support capability, but also eRx and other capabilities such as scheduling and billing typically offered in Practice Management systems. So, caps need to consider what existing health IT capabilities a recipient already has in place and then recognize a cap value for the donated software as well as the services necessary to make the donated software interoperable with existing recipient healthcare IT systems.

IDX suggests that donated EHR software be capped based on fair market value. Furthermore, IDX advocates a lower cap value for EHR software that limits or restricts the recipient from access to other health information technology systems, such as existing billing and scheduling systems of the recipient, or other health information technology systems of other providers the recipient wishes to use. Another suggestion is to treat the cap for the donated EHR software as a not-to-exceed value (like a coupon), where OIG can recognize a base amount for a recognized fair market value, and the recipient can choose to pay the additional cost for software above and beyond what is recognized as an acceptable base amount.

IDX is concerned with statements in the NPRM that over time caps can be lowered due lower cost of EHR systems being deployed overtime. While this may be the case for commodity goods such as broadband services and computer hardware, EHR will be subject to increasing levels of functional capabilities as governed by the CCHIT process, and as such expects the value of EHR to stay the same or increase as the set of required capabilities and other clinical innovations grow.

There is a potential opportunity to incent standards adoption by increasing donation caps commensurate with adoption of certified solutions that incorporate mandated interoperability standards, as well as policies that demonstrate the portability of health information to the greatest extent possible such as the utilization of the EHR within a HIEs. Likewise, donation caps should be lowered when expected interoperability policies and technology cannot be demonstrated by the donating entity.

IDX also recommends that the donating entity be required to offer EHR solutions from a minimum of three vendors for the recipient to select, and require that these solutions be determined via a transparent RFP process. This multi-vendor, open RFP process ensures that competitive market pricing is provided; it allows the recipient to participate in the selection process to ensure that services meet the needs of their clinical practice and it will provide a safeguard against lock-in by the donating entity. The availability of multiple, competing vendor solutions could also provide a mechanism for determining the fair market value for the purposes of calculating the cap value.

11. CMS and OIG ask respondents to comment on criteria for selecting medical staff recipients of donated EHR. (Pg. 59023, col.1) (Pre-Interoperability Electronic Health Records Exception: 411.357w)

IDX appreciates the question, and encourages the Department to consider as broad a criteria for selection as possible since the criteria might limit the use of the eRx tool and therefore not capture the full potential for patient safety and quality improvement. Facilities should be allowed to make this decision based upon their own financial model.

1. Support exemptions that include eRx and EHR, including EHR that include billing and scheduling capabilities

- The definition of an EHR must not explicitly or implicitly be only the EMR/clinical component or combined EMR/Practice management components. It must be any component of information management software used by a physician or medical group to operate the medical practice, i.e. Practice management applications that have additional decision support capabilities that allow for a more robust EHR (eligibility and claims data).

12. CMS and OIG ask respondents to comment on whether the safe harbor for eRx components should extend to software that covers non-drug prescriptions and whether CPOE should be a covered requirement. (Pg. 59021, col. 1; pg. 59022, col. 1) (Electronic Prescribing Exception: 411.357v) (Pre-Interoperability Electronic Health Records Exception: 411.357w)

IDX reminds the Department that in order to achieve patient safety, quality performance, and efficiency goals dependent on the adoption of health information technology, it is essential to permit the optimum use of that technology. Enabling clinicians to use a common tool for many tasks will streamline workflow and encourage the use of IT. For this reason, we recommend that OIG and CMS support the use of eRx and EHR to write all prescriptions / orders, not just for medications, for all patients regardless of payer. This would include requisitions for diagnostic testing, medical supplies, and durable medical equipment.

In addition to this, there needs to be further clarification and understanding around the specific standards/certification on eRx as well as EHR - this standards process could become a barrier to adoption. E-prescribing should not be limited to medication prescriptions, but should include all physician orders including labs, imaging studies, nursing care, allied medical professions' care (e.g. physical therapy), durable medical equipment, supplies, and anything else needed for the patient's care. This more generic concept of 'prescribing' (which, is consistent with United Kingdom's definition in which most doctor ordering is called 'prescribing) should be the focus. E-prescribing (CPOE) in the above sense would allow software to assist with; avoiding medication errors by providing legible and complete prescriptions, with automatic checking for allergies, drug-drug interactions, duplicate therapy, incorrect dose or schedule, and other factors; understanding which medications are currently prescribed or have been used previously for this patient: avoiding the re-use of medications which have failed for this patient in the past; utilizing laboratory and imaging studies according to best practices; understanding which studies have previously been performed for this patient, and when, and accessing those results;- adhering to protocols and guidelines; conforming reliably to payor guidelines, including Medicare's Advance Beneficiary Notification rules; transmitting orders instantly to performing centers; providing audit logs and security controls much better than paper systems.

The assumption that CPOE is only referencing office based CPOS ("Superbill" capabilities for lab, radiology, eRx orders, reporting) could be a limitation/obstacle to the adoption of Community Health Records/EHR which - in and of itself - has significant potential to positively impact the quality of care.

13. CMS and OIG ask respondents to comment on whether the safe harbor should address the issue of whether recipients of donated EHR would intentionally divest themselves of

functionally or technically equivalent technology that they already possess to shift costs to Donors. (Pg. 59018, col. 1; Pg. 59023, col. 1) (Pre-Interoperability Electronic Health Records Exception: Electronic 411.357w)

Understanding the Department's interest in achieving widespread adoption of the EHR throughout the U.S and interest in the success of the American Health Information Community (AHIC) and the associated contracts, IDX suggests that the Department consider including a grandfather clause for clinicians whose existing HIT solutions are not compliant with certification standards. The clause would permit clinicians a one-time opportunity to upgrade their EHR to one that is compliant with the Certification Commission for Health IT EHR certification requirements.

14. CMS and OIG ask respondents to comment on relevance to ensuring EHR are compliant with Public Health Information Network and BioSense preparedness standards. (Pg. 59022, col. 2) (Pre-Interoperability Electronic Health Records Exception: Electronic 411.357w)

IDX is actively supportive of the work being accomplished by the federal government to develop the Public Health Information Network (PHIN). In the ideal state, the PHIN could be greatly enhanced by information gleaned from widespread adoption of EHR, However, the process is slowed by the lack of an interoperability standard, IDX cautions the Department to develop a process that takes into account the current and future standardized solutions.

Additionally, IDX reminds the Department that clinicians and patients may be alarmed by the idea of clinician systems being linked to government systems for Biosurveillance purposes. IDX strongly recommends educating clinicians and the public as to the merits and criteria of public health reporting and the proactive approach to reporting diseases.

Finally, IDX applauds the Department's efforts through the American Health Information Community to raise the bar on Biosurveillance efforts. With the increase in interest the Biosurveillance and disaster management, AHIC and the country will be benefit from the increased emphasis on these efforts and the improvement of the U.S. response to potential biohazards.

15. CMS and OIG ask respondents to comment on whether EHR should be granted the same program and beneficiary protections that exist for eRx. (Pg. 59022, col. 2) (Pre-Interoperability Electronic Health Records Exception: Electronic 411.357w)

IDX encourages the Department to grant EHR the same program and beneficiary protections that exist in eRx, for the reasons we outlined in our answers to Question # 1, which are as follows:

IDX appreciates the opportunity to comment on the issue of necessary nonmonetary remuneration. We are concerned that the distinctions drawn between software and hardware effectively do not include hardware from the EHR safe harbor, but includes it in the eRx safe harbor. We understand the legal challenges outlined by the provisions in the Medicare Modernization Act; however the distinction does not seem practical, especially in a context where the EHR must include eRx to qualify for safe harbor.

For further clarification, IDX supports including EHR software, including any ancillary systems/components such as billing, scheduling and practice management in the definition of

permitted donations so long as such software includes the required components of eRx software. IDX believes that providers should have maximum choices in determining the vendor applications that will be donated. Most vendor solutions are integrated EHR applications rather than stand-alone eRx modules. Expanding the definition of what may be donated will ensure that competition among vendors, as one of the preferred vendors for the donated solution will be maximized. This will help ensure that donors have many choices to drive the highest value solutions for donation to providers. The definition of EHR must not explicitly or implicitly be only the EHR/clinical component or combined EMR/Practice management components. It must be any component of information management software used by a physician or medical group to operate the medical practice, e.g., Practice Management applications that have additional decision support capabilities that allow for a more robust EHR (patient demographic, eligibility and claims data). Data from billing and scheduling systems is foundational data by which portability of patient information is established. Any incentive that does not recognize these existing capabilities as integral prerequisites to the exchange of clinical health information will be counterproductive.

Additionally, with respect to connectivity services, drawing the distinction on donated versus purchased connectivity and internet services is difficult to parse out, as providers would be forced to identify which instances of internet usage where strictly for eRx, as opposed to other services. Practices need guidance on connectivity as much as on hardware or software. We suggest that connectivity should be a defined benefit of the agreement in the safe harbor, as opposed to a defined contribution.

16. CMS and OIG ask respondents to comment on best process for determining the value of donated technology. (Pg. 59022, col. 3) (Pre-Interoperability Electronic Health Records Exception: Electronic 411.357w)

IDX is concerned that developing a process for determining the value of donated technology may be cumbersome and unnecessary, which could slow down implementations and create unnecessary challenges for the government and the healthcare industry. Instead, IDX recommends allowing fair market value to drive the value.

In addition, IDX supports the NPRM requirement that donated software/systems cannot be used to replace existing capabilities already in place at the physician practice, which should be taken into account when assessing the value of the donated software. For example, an integrated EHR system with a scheduling and billing functionality should not be included in the fair market value estimate when the recipient already has an existing scheduling and billing IT system. Furthermore, the donated software should be interoperable or made to be interoperable with existing recipient health IT systems, and can include the integration services necessary to ensure interoperability with other IT systems deemed necessary by the recipient. In summary, the donated software should be seen as providing extensibility to existing IT capabilities already in place in the physician practice.

IDX also refers OIG to the responses regarding caps in Questions # 5, # 10 and # 22.

17. OIG asks respondents to comment on how the government should protect federal healthcare programs and recipients from being the victims of cost shifting for EHR development. (Pg. 59023, col. 1)

IDX appreciates the concern regarding donors shifting the cost of EHR to federal healthcare programs. Studies published by Connecting for Health, Health Affairs and EHR vendors indicate that there is a return on investment (ROI) for ambulatory EHR. The challenge is that the ROI varies with the size of the physician practice and is subject to other factors, such as how a practice recognizes labor productivity savings. The Department should investigate calculating an overall donation cap that recognizes the total cost of ownership for a specified period of time and practice size, whereby the Department could mandate EHR related savings that should be realized over the period, and factor in those future benefits relative to the cap provided to the donating entity. This builds in cost shifting protection since the Department can recognize "minimum" benefits to be realized in the outgoing years, and it should incentives the donating entity and recipient to achieve those benefits. In addition, financial risk beyond the implementation phase should be mitigated as pay for performance incentives are implemented.

18. CMS and OIG ask respondents to comment on the covered and noncovered entities and potential alternative conditions for specific categories of donors. (Pg. 59023, col. 1,3) (Pre-Interoperability Electronic Health Records Exception: Electronic 411.357w)

IDX is concerned with the statement in the NPRM (Federal Register Vol. 70, No.195, Oct. 11, 2005, page 59023, column one) that reads: "Moreover, hospitals, group practices, PDP sponsors, and MA organizations are potentially in a better position to promote widespread use of electronic health records technology that has the greatest degree of openness and interoperability." In practice the amount of fragmentation in our marketplace today is due in part to these and other entities that view patient information as proprietary, and access to the information silos they create serve as a means of locking in physicians and patients. To suggest the contrary would not explain the reluctance of these and similar entities from forming health information exchanges that would allow patients and physicians to freely choose services based on quality and efficiency, without the limitation of the resulting health information to be made available in a timely and effective manner. In the context of comparing these entities with ancillary services such as laboratories relative to embracing portability of patient information wherever and whenever providers that are delivering care need it, there is no difference between laboratories or the entities mentioned above.

As for the list of donors, IDX encourages the Department to consider including Pharmaceutical Manufacturers and Integrated Delivery Networks, especially if these entities are affiliated with neutral third party health information exchanges (HIEs) or regional health information exchanges and that the donation in question will be utilized in conjunction with the HIEs in which the donor is engaged.

The development and deployment of HIEs is a public policy priority articulated by both the President and Congress. Including HIEs as appropriate donors for purposes of safe harbor could incent physician participation due the neutral governance and interoperability enforcement provided by the HIEs. Given that physicians typically have privileges at multiple hospitals, HIEs provide a natural infrastructure for interconnecting multiple competing entities with recipients cost effectively. HIEs could also provide a centralized purchasing and administration of commodity services such as connectivity and training services.

In the eHealth Initiative Annual Survey of State, Regional and Community-Based Health Information Exchange Initiatives and Organizations, September 2005, of the 109 qualified HIEs surveyed, 25 HIEs are already fully operational, with another 40 in the implementation phase. OIG

could review the governance models of these HIEs for recommended regulations that mitigate the risk of fraud and abuse. Coupling HIE AKS protection with the existing Stark exemption for Community Wide Health Information Systems would provide the effective healthcare IT adoption incentives based on HIE interoperability policies that require portability of health information as a primary goal.

Providing anti-kickback protection for groups like pharmaceutical companies that may invest in multi-stakeholder entities such as HIEs would allow the private sector to invest in creating community-wide health information infrastructure, without concerns of violating anti-kickback statutes. OIG should consider the governance, interoperability policy and technology guidelines put forth by eHI as a model for providing HIEs that would provide the governance, policy and operating constructs that protect against fraud and abuse, while allowing donations from a broader group of donors that otherwise would not consider donating software, hardware or recognized services.

19. CMS and OIG ask respondents to comment on whether the safe harbor should protect additional software applications, provided eRx, and EHR are the core functions of the protected software, and whether CPOE should be included as a requirement. (Pg. 59023, col. 3) (Pre-Interoperability Electronic Health Records Exception: Electronic 411.357w)

IDX suggests that the scope of solutions within the safe harbors should be expanded to include at least registration, scheduling and practice management, as this functionality also promotes the same public benefits as eRx and EHR (greater system efficiency and reduced variance in health care delivery and results). In addition, the data generated by these systems is the foundation or core data from which an electronic health record can be constructed, and its implementation is a pre-requisite for valid health data exchange.

20. CMS and OIG ask respondents to comment on whether the safe harbor should include other categories of donors and recipients. (Pg. 59023, col. 1,3) (Pre-Interoperability Electronic Health Records Exception: Electronic 411.357w)

IDX encourages the Department to broaden the list of recipients to be consistent with its usual broad view of healthcare delivery by using the generally accepted term within the Department "prescribing healthcare professionals." Other recipients should include secondary and tertiary care facilities, such as a skilled nursing or long term care facilities.

As for the list of donors, IDX encourages the Department to consider including Pharmaceutical Manufacturers, medical device manufacturers and Integrated Delivery Networks, especially if these entities are affiliated with neutral third party health information exchanges (HIEs) or regional health information exchanges.

The development and deployment of HIEs is a public policy priority articulated by both the President and Congress. Including HIEs as appropriate donors for purposes of safe harbor could incent physician participation due the neutral governance and the interoperability enforcement provided by the HIEs. Given the physicians typically have privileges at multiple hospitals, HIEs provides a natural infrastructure for interconnecting multiple competing entities with recipients cost effectively. HIEs could also provide a centralized purchasing and administration of commodity services such as connectivity and training services.

In the eHealth Initiative Annual Survey of State, Regional and Community-Based Health Information Exchange Initiatives and Organizations, September 2005, of the 109 HIEs qualified in the survey, there are already 25 HIEs fully operational, with another 40 in the implementation phase. OIG should review the governance models of these HIEs for recommended regulations that mitigate fraud and abuse risk. Coupling HIE AKS protection with the existing Stark exemption for Community Wide Health Information Systems would provide the effective healthcare IT adoption incentives based on HIE interoperability policies that require portability of health information as a primary goal.

Providing anti-kickback protection for groups like pharmaceutical companies that may invest in multi-stakeholder entities such as HIEs would allow the private sector to invest in creating community-wide health information infrastructure, without concerns of violating anti-kickback statutes. OIG should consider the governance, interoperability policy and technology guidelines put forth by eHI as a model for providing HIEs that would provide the governance, policy and operating constructs that protect against fraud and abuse, while allowing donations from a broader group of donors that otherwise would not consider donating software, hardware or recognized services.

21. OIG asks respondents to comment on whether the safe harbor should enhance fraud and abuse protections to allow donors to pre-select recipients based on identifiable criteria. (Pg. 59024, col. 1)

IDX understands that a transparent market would allow donors to pre-select recipients, but OIG would need to consider criteria other than referrals to allow pre-selection. For example, OIG should be concerned about pre-selection criteria that may result in monopolizing patients in a geographical area, especially in the absence of interoperability policies that may result in the creation of proprietary networks of patient information. IDX is also concerned about providing equitable access to safety net providers or rural market providers as recipients of donated EHR and suggests including equal access language to ensure that these entities could participate as recipients of donate eRx or EHR.

22. OIG asks respondents to comment on whether the safe harbor should identify an overall donation cap. (Pg. 59024, col. 2)

IDX appreciates the complexity of this item given the many concerns regarding the method of defining an economic cap. The Department needs to take into consideration the following factors that may impact the market and providers, in particular:

1. A cap could set the price indirectly;
2. Any cap would need to cover not just the hardware, but the connection, software, support and other related service for eRx and EHR;
3. Discerning the different price points between functions such as eRx and EHR, as well as products with both capabilities already integrated, including the recognition of other scheduling and billing functions.
4. Determining the manager of the service (hospital, other provider, etc.)
5. Considerations for setting or review of specific price points given volatility in the market and regional market pricing differences.

IDX generally supports the Department's view of providing caps as a safeguard against fraud and abuse. The practical concern is in establishing the value of the donated multi-functional hardware and connectivity services. IDX suggests that donated multi-functional hardware and connectivity be capped based on fair market value, since there is transparent pricing for these types of goods in the marketplace today. Another suggestion is to treat the cap for multi-functional hardware and connectivity services as a not-to-exceed value (like a coupon), where OIG can recognize a base amount for a recognized fair market value, and the recipient can choose to pay the additional cost for hardware or connectivity services above and beyond what is recognized as an acceptable base amount. The way to ensure this is to cap donated software at no more than a predetermined dollar amount. Up to that dollar amount could be used for either the purchase of donated software or for any other software equivalent to the donated software, which could be shown to have a path toward integration with the donated software (without restriction by the donated software vendor) within a reasonable period of time. In order to determine the value of the cap, determine the average cost of the software system/module to a dollar value per physician, with value to be adjustable given factors such as inflation, the prevalence of accepted standards or certification requirements that typically lead to increased capability/content.

IDX is concerned with statements in the NPRM that state over the long-term, caps can be lowered due lower cost of EHR systems being deployed over time. While this may be the case for commodity goods such as broadband services and computer hardware, EHR will be subject to increasing levels of functional capabilities as governed by the CCHIT process, and as such expect the value of EHR to stay the same or increase as the required set of capabilities or other clinical innovations grow.

There is a potential opportunity to incent standards adoption by increasing donation caps commensurate with adoption of certified solutions that incorporate mandated interoperability standards, as well as policies that demonstrate the portability of health information to the greatest extent possible such as the utilization of the EHR within a HIEs. Likewise, donation caps should be lowered when expected interoperability policies and technology cannot be demonstrated by the donating entity.

IDX also recommends that the donating entity be required to offer EHR solutions from a minimum of three vendors for the recipient to select, and require that these solutions be determined via a transparent RFP process. This multi-vendor, open RFP process ensures that competitive market pricing is provided; it allows the recipient to participate in the selection process to ensure that services meet the needs of their clinical practice as well as provides a safeguard against lock-in by the donating entity. The availability of multiple, competing vendor solutions could also provide a mechanism for determining the fair market value for the purposes of calculating the cap value.

23. OIG asks respondents to comment on whether there is data available that would reinforce or challenge the proposed rule, particularly with respect to the expected impact on adoption rates. (Pg. 59024, col. 2)

IDX is concerned that Safe Harbors may be used as an alternative to providing real and substantial incentives to providers for providing quality delivery of healthcare, which is enabled by EHR. Data regarding successful EHR implementations points to physician readiness and acceptance to make the necessary workflow and operational business changes required when implementing EHR. Providing free hardware or software is not enough, as noted in several giveaway projects, such as

Wellpoint's eRx experiment in California. In that pilot, free eRx software and hardware was provided to physicians in what was later viewed as a qualified failure, resulting in the now famous quote, "free is not cheap enough."

More importantly, safe harbors have an enormous downside in two respects. First, it could stop the existing momentum of ambulatory EHR adoption as physician expectations of "free" software freezes current market momentum. Second, it puts focus on EHR adoption without the commensurate interoperability policies that ensure portability of health information, resulting in proprietary solutions that lock-in incumbent vendors and provider referral networks and increasing barriers to a transparent efficient healthcare market.

IDX suggests that both EHR adoption and our national goals for an interoperable healthcare infrastructure could best be served by continuing to support the development of HIEs, especially where other private sector donors would be willing to participate given the proper AKS changes that support participation in HIEs.

IDX also asks the Department to acknowledge stakeholder concerns that providers with an existing electronic health record or eRx system (early adopters) not be subjected to any perceived financial penalty as a result of making an initial EHR investment despite the safe harbor protections for recipient equipment upgrades.

24. OIG asks respondents to comment on expanding AKS to include Community-Wide Health Information systems as set forth in section 1877 of the Act (Pg. 59024, col. 2)

The development and deployment of HIEs is a public policy priority articulated by both the President and Congress. Including HIEs as appropriate donors for purposes of safe harbor could incent physician participation due the neutral governance and the interoperability enforcement provided by the HIEs. Given the physicians typically have privileges at multiple hospitals, HIEs provides a natural infrastructure for interconnecting multiple competing entities with recipients cost effectively. HIEs could also provide a centralized purchasing and administration of commodity services such as connectivity and training services.

In the eHealth Initiative Annual Survey of State, Regional and Community-Based Health Information Exchange Initiatives and Organizations, September 2005, of the 109 HIEs qualified in the survey, there are already 25 HIEs fully operational, with another 40 in the implementation phase. The recognition of these 65 operating HIE's, plus an addition 40-plus communities in the process of forming, suggests that dedicated parties have been able to silence the critics of the community-wide safe harbor by being able to define what "community-wide means", as well as working through the challenges of providing appropriate governance models that support all stakeholders. IDX recommends that OIG review the governance models of these HIEs for recommended regulations that mitigate the risk of fraud and abuse. Coupling HIE AKS protection with the existing Stark exemption for Community Wide Health Information Systems would provide the effective healthcare IT adoption incentives based on HIE interoperability policies that require portability of health information as a primary goal.

Providing anti-kickback protection for groups like pharmaceutical companies that may invest in multi-stakeholder entities such as HIEs would allow the private sector to invest in creating community-wide health information infrastructure without concerns for violating anti-kickback

statutes. OIG should consider the governance, interoperability policy and technology guidelines put forth by eHI as a model for providing HIEs with the governance, policy and operating constructs that protect against fraud and abuse, while allowing donations from a broader group of donors that otherwise would not consider donating software, hardware or recognized services.