CMS-1303-P-17 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Ms. Anne Canfield **Date & Time:** 12/12/2005

Organization : Rx Benefits Coalition

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1303-P-17-Attach-1.DOC

Rx BENEFITS COALITION

Safety + Affordability + Innovation

December 13, 2005

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

Office of Inspector General
Department of Health and Human Services
Attention: OIG–405–P
Cohen Building – Room 5246
330 Independence Avenue, SW.,
Washington, DC 20201.

SUBJECT: Proposed rules concerning (1) exceptions to the physician self-referral rules for certain electronic prescribing and electronic health records arrangements; and (2) a safe harbor for certain electronic prescribing and electronic health records arrangements under the anti-kickback statute

Dear Madams/Sirs:

The Rx Benefits Coalition ("RxBC")[1] is a coalition representing a diverse group of employers and other payers and providers of prescription drug benefits committed to ensuring that consumers have access to safe and affordable prescription drug services. The RxBC appreciates the opportunity to submit comments in response to the Department of Health and Human Services' Center for Medicare and Medicaid Services (CMS) Notice of Proposed Rulemaking (CMS-NPRM), and the Office of Inspector General (OIG) Notice of Proposed Rulemaking (OIG-NPRM), each dated October 11, 2005.

[1] *See* www.rxbc.org for a list of members.

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This letter comments on the following sections of the CMS-NPRM: I. "Background"; II.A "Electronic Prescribing Exception: §411.357(v)"; II.B.2 "Post-Interoperability Electronic Health Records Exception: §411.357(x)"; and IV. "Regulatory Impact Statement." The letter comments on the following sections of the OIG-NPRM: I. "Background"; II.A "Electronic Prescribing Safe Harbor Required Under Section 101 of the MMA: Paragraph (x)"; and II.B.2 "Proposed Post-Interoperability Safe Harbor."

In our comment letter today we wish to make four basic points:

1. Adoption of comprehensive electronic information technology systems, beginning with the adoption of a fully-integrated e-prescribing system and interoperable electronic health records "(EHRs"), will not only improve the quality of care, but also reduce health care costs substantially.
2. The donation of effective technology systems will not induce abuses. On the contrary, potential donors will donate systems because of the manifest benefits in improved quality of care and reduced health care costs that will result from the implementation of effective technology systems – goals we believe that were envisioned with the enactment of the physician self-referral and anti-kickback statutes. Moreover, in addition to ensuring appropriate utilization of services, technology systems will enable CMS to more effectively administer the Medicare program generally, and provide enforcement officials with the tools necessary to identify and track abuses, if they occur.
3. The proposed physician self-referral prohibition and anti-kickback rules pose major impediments to the adoption of comprehensive, interoperable health care information technology solutions because these rules effectively prohibit legitimate and beneficial arrangements between hospitals and their staff physicians, and among other donors and recipients.
4. The exceptions to the physician self-referral prohibition proposed in the CMS-NRPM, and the safe harbor proposed in the OIG-NRPM, are too narrowly drawn, thereby impeding the adoption of interoperable health information technologies and stalling the reengineering of the health system that is essential to improving the quality of care in the United States.

In summary, we urge that (1) CMS provide very broad exemptions to physician self-referral prohibition that are clearly defined, and (2) OIG make the safe harbors for the anti-kickback laws much wider so that comprehensive health information technologies can be adopted, particularly since these systems will improve health care quality, reduce costs, and will work to prevent fraud and abuse, not aid and abet it.

I. Adoption of comprehensive electronic information technology systems, beginning with the adoption of a fully-integrated e-prescribing system and interoperable EHRs, will not only improve the quality of care, but also reduce health care costs substantially.

Our Fragmented System Costs Lives as Well as Money

Although the U.S. health care system is costly, American companies and consumers are buying services from an error-riddled system. In 1999, the National Academy of Science Institute of Medicine (IOM) published a study estimating that 44,000 to 98,000 patients die annually due to medical error. The IOM research found that between 2.9 percent and 3.7 percent of patients admitted to a hospital will fall victim to a possibly fatal medical error.[2] That is just hospital errors; if only half of 1 percent of the 31.5 million annual outpatient procedures result in a "preventable adverse event," more than 100,000 people are also at risk[3] each year. In 2003, the National Committee on Quality Assurance (NCQA) came to a similar conclusion. The NCQA reported that 57,000 Americans die annually because they do not receive appropriate care for their symptoms.[4]

Medical errors often result from the fragmented, non-automated nature of America's health system. Physicians and hospitals frequently do not have complete patient medical histories when they must make critical care decisions.

A Growing Affordability Gap and a Growing Quality Gap

Conventional management of medical paperwork is not only unnecessarily risky – it is expensive. Health care spending is growing at a rate that threatens the affordability of health care for millions.[5] Employers and employees face double-digit annual increases in the cost of health insurance premiums – several times the annual inflation rate. The IOM report estimated that eliminating preventable medical errors alone would save $17 billion annually. Eliminating unnecessary tests would bring more savings; approximately 20 percent of tests are reordered because previous results are not available.

Americans pay the highest price for health care in the world. Adults, however, receive only about half of the care recommended for them. The "First National Report Card on Quality of Health Care in America" issued by the Rand Corporation shows that better information flow between patients and providers and between providers will save lives.[6]

Here are some examples from Rand's research:

- Less than one quarter of diabetics measure their blood sugar levels regularly, putting them at risk for kidney failure, blindness, and amputation of limbs
- Patients with hypertension receive less than two-thirds of recommended care, contributing to 68,000 deaths annually due to poor blood pressure control

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[2] Institute of Medicine, "To Err is Human: Building a Safer Health System," published November 1999 and available at www.iom.edu, page 1.

[3] Richardson, Berwick, Bisgard, Letter to the Editor regarding "The Institute of Medicine Report on Medical Errors", New England Journal of Medicine, August 2000.

[4] National Committee for Quality Assurance, "The State of Health Care Quality: 2003", published in 2003 and available at www.ncqua.org, page 6.

[5] PriceWaterhouseCoopers, "Cost of Caring: Key Drivers of Growth in Spending on Hospital Care", commissioned by the American Hospital Association and available at www.aha.org.

[6] Rand Health, "The First National Report Card on Quality of Health Care in America", published April 2004 and available at www.rand.org, pages 2 and 3.

- Over one-third of seniors are not vaccinated against pneumonia, which causes 10,000 elderly deaths every year.

Unneeded tests, preventable errors, unnecessary hospitalizations, remedial care to counteract the impact of medical error, and other waste will cost $7.4 trillion over the next decade. *Many of these mistakes are errors of omission.* NCQA blames poor use of technology, lack of collaboration between health care professionals, payment systems that compensate for any type of care – not results – and a need to engage individuals in their treatments and therapies.[7] Whether medical errors result from omission or mistake, the system must change.

Expensive and Ineffective "Over Treatment"

Medical knowledge is exploding, and moving into new areas of diagnosis and treatment. Every medical professional tries to keep abreast of the latest finding in his or her field, but the daily demands of providing care to patients limit the time available for study. The nation's health care quality problem is not due to lack of availability of information about the latest medical advances. On the contrary, information is overwhelming medical professionals, and medical practices are not keeping up with the latest knowledge. There are approximately 60,000 medical studies done each year, but it is not possible for medical professionals to review or use all of this information.

Every study advocates new advances and medications with limited advice on the most effective use; rather than replacing old practices, these procedures are being added to the physicians' list of treatments. Health care providers thus receive new tools of their trade without objective measures of effectiveness. The result is "over treatment." A physician orders more tests and treats a patient both the tried-and-true "old way" as well as the possibly beneficial "new way." The accelerated rate of change in medical practices exacerbates the inefficiencies of a payment system that compensates for treatment, regardless of outcome, and provides generous court settlements to defendants who prove that the medical professional who treated them disregarded established practices.

Transformation is More Likely With Individuals in Personal Health Care

E-prescribing and EHRs alone cannot address patient-related error, such as the failure of patients of take medication as prescribed. One prescription in five is never filled. About 50 percent of all patients do not take medications according to their physician's instructions.[8] Patient non-compliance is not just a problem with medications. Physicians often give recommendations for diet, exercise, and symptom monitoring which patients ignore. As current studies are showing, the most expensive medical system in the world does not guarantee quality. Unless patients become more involved in their care, the system will remain broken.

Medical transformation goes well beyond data base management and e-prescribing. A transformed health care system will use automation, information, and education to

[7] National Committee for Quality Assurance, note 4, above, pages 7 and 19.
[8] "Beep! It's time to take your pill", Chicago Tribune, June 27, 2004.

engage patients in their health care. Comprehensive medical information technology includes patient reporting and monitoring.

Individualized care is the ultimate goal. One size fits all will be an anachronism. Some approaches will use high-tech breakthroughs, such as diagnosis and preemptive treatment through genetic testing and DNA-level designer drugs. Others will rely on the common sense practice of personal engagement in healthy living through lifestyle, education and participation in health management.

The Solution: E-Health

E-health is everything from automated data maintenance that ends duplicative records, computerized home monitoring that cuts back office visits, e-prescriptions that ensure accuracy and save time and money, bar code prescription orders that track individual prescriptions and provide automatic renewals, EHRs that enable collaboration between health care professionals, to patient monitoring and reporting to ensure patient compliance, to a reengineering of the payment systems so that medical professionals and their patients are focused on "outcomes." A fully-integrated e-prescribing system and interoperable EHRs are two essential tools necessary to begin the reengineering of the health care system.

Both the CMS-NPRM and the OIG-NPRM recognize the benefits of the adoption of health information technologies. Both the CMS-NPRM and the OIG NPRM refer to the analysis presented in the E-prescribing NPRM of February 4, 2005, and state that they "expect that donors may experience net savings with electronic prescribing in place and patients would experience significant positive health effects." (70 Fed. Reg. at 59193 and 59025, respectively).

In addition, the CMS-NPRM states that, "There are numerous studies reporting that EHRs in the ambulatory setting can result in a substantial improvement in clinical process." (Ibid.). Among those cited benefits are (1) reducing unnecessary or duplicative lab and radiology test ordering, (2) lowering ancillary test charges, (3) reducing hospital admissions due to adverse drug events, (4) reducing excess medication usage, (5) reducing administrative inefficiency and paper handling, and (6) decreasing physician visits.

As the CMS-NPRM concludes in summarizing the current literature,

> "These studies show a consistent pattern of clinical utilization reductions that have been reported to arise from electronic health records use in ambulatory settings. Although financial estimates were not performed in these studies, these utilization reductions could yield savings that accrue to Medicare because of its use of volume-based payments for ambulatory and inpatient care. Other studies have estimated that electronic health records in the ambulatory setting would save $78 billion to $112 billion annually, across all payors." (70 Fed. Reg. at 59193).

Widespread adoption of health information technologies is essential to generating substantial savings to the healthcare system, as well as improving the quality of care. Rather than increasing utilization, the evidence shows that it in fact accomplishes the reverse.

II. The donation of effective technology systems will not induce abuses. On the contrary, potential donors will donate systems because of the manifest benefits in improved quality of care and reduced health care costs that will result from the implementation of effective technology systems – goals we believe that were envisioned with the enactment of the physician self-referral and anti-kickback statutes. Moreover, in addition to preventing unnecessary utilization of services, technology systems will enable CMS to more effectively administer the Medicare program generally, and provide enforcement officials with the tools necessary to identify and track abuses, if they occur.

CMS Administrator Dr. Mark McClellan stated in announcing the proposed regulations, "Restrictions on relationships between physicians and other health care entities are very important to 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."[9]

Yet, despite Dr. McClellan's statement, the CMS-NPRM is replete with statements of concern that the health technology exception to the physician self-referral prohibition could open the door to fraud and abuse. CMS summarized these concerns about self-referrals in an earlier NPRM on physician self-referral (63 Fed. Reg. 1659, at 1661; January 9, 1998), stating that there is harm when financial self-interest leads to more extensive and higher priced services than a patient actually needs.

In the same vein, the OIG-NPRM repeatedly states concern that the health technology exception to the anti-kickback laws could open the door to fraud and abuse. For example,

> "The OIG has a longstanding concern about the provision of free or reduced price goods or services to an existing or potential referral source. There is a substantial risk that free or reduced price goods or services may be used as a vehicle to disguise or confer an unlawful payment for referrals of Federal health care program business. Financial incentives offered, paid, solicited, or received in exchange for generating Federal health care business increase the risks of, among other problems: (i) Overutilization of health care items or services; (ii) increased Federal program costs; (iii) corruption of medical decision making; and (iv) unfair competition." (70 Fed. Reg. at 59016).

The question for the present rulemaking then becomes whether the Medicare program and healthcare more generally should forego the benefits of adopting comprehensive health information technologies because of the misguided concerns about self-referral or anti-kickback violations.

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[9] HHS Press Release, October 5, 2005.

In searching for a resolution, three basic points deserve emphasis:

- Many of the benefits of health information technologies include a *reduction* in utilization of unneeded healthcare services, as was summarized above.
- Other benefits of health information technologies include cost reductions that take various forms. Indeed some commentators conclude that the market failure of the health sector to adopt information technologies more widely relates to concern among private entities about the impact of some of those cost reductions on their own business.[10]
- If implemented correctly, comprehensive and fully integrated health technology systems will actually advance the goals intended by the physician self-referral and anti-kickback rules – goals that are shared by many potential technology donors -- by reducing inappropriate or unnecessary utilization and improving efficiencies.

Fully integrated technology systems will actually work to prevent fraud and abuse before it occurs, but should improper transactions occur, the systems will also enable enforcement officials to more precisely track data information related to abuses on a timely basis. There is substantial overlap between the benefits of widespread adoption of healthcare technologies and the goals of CMS and OIG in enforcing the laws on physician self-referrals and kickbacks – both seek to decrease unnecessary or inappropriate utilization and improve the quality and cost-effectiveness of health care.

III. The proposed physician self-referral prohibition and anti-kickback rules pose major impediments to the adoption of comprehensive, interoperable health care information technology solutions because these rules effectively prohibit legitimate and beneficial arrangements between hospitals and their staff physicians, and among other donors and recipients.

Numerous studies have explored why adoption of comprehensive information technologies in the healthcare sector has lagged technology adoption in so many other sectors of American life. Two related reasons have emerged: First, the benefits of adopting comprehensive and interoperable healthcare technologies accrue largely to parties other than those who must pay for the adoption. Indeed, one recent analysis suggests that precisely the benefits of interoperable health information technologies may lie at the core of the problem: few healthcare participants have an economic incentive to pay for expensive technologies that will result in a reduction of utilization of their services unless these technologies also provide offsetting benefits.[11]

Physicians in particular play a key role in the adoption of health information technologies. They often stand at the center of the relationship between the patient on the one hand and the myriad of healthcare providers – hospitals, pharmacies, laboratories,

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[10] See, e.g., J.D. Kleinke, "Dot-Gov: Market Failure and the Creation of a National Health Information Technology System," *Health Affairs*, vol. 24, No. 5, September/October 2005, pp. 1246-1262.
[11] Ibid.

and health insurers – on the other. Yet, it frequently makes little economic sense for an individual physician to adopt expensive technologies for e-prescribing and EHRs. As one recent study reports:

> "Key surface barriers to EHR use that emerged as persistent themes from our interview data included high financial costs, slow and uncertain financial payoffs, and high initial physician time costs. Underlying barriers included difficulties with technology, complementary exchanges and support, electronic data exchange, financial incentives, and physicians' attitudes."[12]

The CMS-NPRM itself cites the following from another study to illustrate some of the barriers to adoption:

> "The greater marvel is that any physician, at his or her personal expense, would install a system that ...saves money for every health care stakeholder except the adopting physician."[13]

Second, laws and regulations, but particularly the prohibition on physician self-referrals and the anti-kickback laws, create a barrier against the shifting of financial burdens to permit those who receive the greatest economic benefit from the technology --- in terms of cost savings, efficiencies and reduced utilization – to invest and bear the economic cost of its implementation. Unless this appropriate alignment of costs and benefits is allowed to occur in the health care marketplace without artificial regulatory constraints impeding the flow of technology investment to its best and highest use, the hope and promise of technological transformation of the health care system will remain unrealized.

A Congressional Research Service report notes,

> "Health IT experts have identified several federal laws that may unintentionally impede the development of electronic connectivity in health care. Because these laws do not directly address health IT, health care providers are uncertain about what would constitute a violation or create the risk of litigation. The Medicare physician self-referral (Stark) law (42 U.S.C. § 1395nn) and the anti-kickback law (42 U.S.C § 1320a-7b(b)), which covers all federal health care programs, are of chief concern."[14]

In other industries, vendors of hardware and software might provide financial incentives to early adopters of their technologies in order to accelerate the adoption process. Similarly, businesses may provide software or financial incentives to their partners who adopt mutually beneficial technologies. In the mortgage industry, for example, some of the largest purchasers of home mortgages have provided to mortgage brokers – much smaller companies -- both the software for automated underwriting and ancillary systems

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[12] Robert H. Miller and Ida Sim, "Physicians' Use of Electronic Medical Records: Barriers and Solutions," *Health Affairs*, vol. 23, No. 2, March/April 2004, pp. 116-126, at p. 119.
[13] Kleinke, note 9, above, cited in NPRM, 70 Fed. Reg. at 59194.
[14] C. Stephen Redhead, Health *Information Technology: Promoting Electronic Connectivity in Healthcare*, Congressional Research Service RL32858, April 13, 2005, p. CRS-7.

and financial incentives for use of the software and systems. As a result, most mortgage originations occur through automated underwriting systems rather than through the paper-based processes that were the norm even a few years ago.

This rational burden shifting is largely prevented in the healthcare industry by the CMS rules prohibiting physician self-referrals and by the OIG anti-kickback rules. Thus, under the physician self-referral rules, a physician generally may not make referrals for certain designated health services to an entity with which the physician has a financial relationship. If an entity provides goods and services that have financial value – such as software, hardware, or services supporting health information technologies – to a physician who refers patients to that entity, the physician self-referral or anti-kickback rules may be contravened. Fear of contravening the prohibitions creates a significant obstacle because of the draconian penalties that may attach to Medicare fraud and abuse violations, an arena already fraught with uncertainty and risk.

For example, the proposed CMS and OIG rules each would limit donations of equipment and services to only hospital medical staff members, thereby precluding donations to "physicians who already practice at other hospitals" since this might induce them "to join the medical staff of a different hospital." This is but one example of the unnecessary legal limitations imposed under the proposed rules that will deter potential donors covered by these rules from embarking on such a program, particularly when the issues of proof are considered.

Hospitals interested in leveraging technology solutions should be allowed to reap the benefit of their investment by offering to connect all physicians who practice at that hospital, whether or not they are moving from another location. The same principle should apply to other potential donors, particularly since effective technology systems will reduce health care costs and enable HHS/CMS/OIG to better detect and prevent fraud and abuse.

IV. The exceptions to the physician self-referral prohibition proposed in the CMS-NRPM, and the safe harbors proposed in the OIG-NRPM, are too narrowly drawn, thereby impeding the adoption of interoperable health information technologies and stalling the reengineering of the health system that is essential to improving the quality of care in the United States.

The government itself is unlikely to provide sufficient financial support to physicians and other providers to adopt health information technologies. On the other hand, the physician self-referral prohibition and anti-kickback rules create major obstacles against provision of funding from interested private sector parties for the technologies that potentially could bring major benefits to patients, the healthcare sector, and the administration of Medicare.

It is in recognition of this problem that the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires that CMS and the OIG promulgate rules that create exceptions to the physician self-referral prohibition and anti-kickback laws, respectively. The CMS-NPRM seeks to implement the part of that requirement

concerning the physician self-referral prohibition, while the OIG-NPRM seeks to implement the part concerning the anti-kickback rules.

Unfortunately, CMS and the OIG propose (1) exceptions to the physician self-referral prohibition, and (2) safe harbor provisions, that are so narrow so that they will not have any real utility in the market. The anti-kickback safe harbors proposed by OIG and the physician self-referral exceptions proposed by CMS each take a single-minded approach in trying to anticipate and prevent even the most remote "inducement" to a physician, without taking into account market realities or the original intent of the anti-kickback and self-referral laws. The anti-kickback provisions were enacted to prevent kickbacks or other arrangements whereby a physician would receive a quid pro quo from a referral source in exchange for a referral of business for which Medicare or Medicaid was the payor. Similarly, the self-referral law sought to prevent inappropriate incentives to refer patients for potentially unnecessary services by making it unlawful for physicians to refer business to entities with which they had a "financial relationship" - defined broadly so as to avoid loopholes, but intended to catch primarily arrangements where physicians had a stake in the profits to be generated from tests or procedures on patients they referred. Since the laws cast a broad net, the jurisprudence that has grown up around these laws has created an environment where no cost/benefit analysis exists.

For example, all agree that a hospital providing technology equipment, software and services to the physicians on its medical staff provides significant benefit to all players in the healthcare system (government, payors, patients, physicians) by enhancing safety and reducing costs. It is also clear that were a hospital to make such technology available, physicians would not have an incentive to over-refer in the ways the anti-kickback and self-referral laws sought to prevent, because they do not stand to gain anything more by referring more (it is clearly unlawful to make such a donation in exchange – i.e., as an inducement – for a commitment to refer in the future). This key distinction has been ignored. Therefore, while significant benefits to the system could accrue, hospitals historically have felt constrained to provide such technology due to concerns about over-zealous anti-kickback enforcement or a technical violation of the physician self-referral rule due to the over-broad definition of "financial relationship."

It is therefore vital for both OIG and CMS to take a more practical approach to interpreting these laws, and provide safe harbors/exceptions and related guidance so the U.S. healthcare system can progress.

The limited scope of the two proposed rules is seen in the regulatory analysis that appears in the CMS-NPRM itself. The CMS-NPRM cites one study that found, for example, "the average initial cost of implementing an EHR system to be $33,000 per physician, with maintenance costs of $1,500 per physician per month, numbers which 'would translate into about a 10 percent reduction in take-home pay each year for most primary care practices' if amortized over 5 years."[15]

[15] Gans, D., et al., "Medical Groups: Adoption of Electronic Health Records and Information Systems," *Health Affairs*, vol. 24, No. 5, September/October 2005, pp. 1323-1333.

By contrast, the CMS-NPRM states that, "We estimate that, at most, each physician would receive a total of $3,000 worth of donated items and services under the proposed Exceptions [to the physician self-referral prohibition]." (70 Fed. Reg. at 59195). It is little wonder that the NPRM estimates a negligible cost for its proposed rule, of approximately $36 million annually. On the other hand, the NPRM also foresees little benefit from the proposed rule; it estimates that the proposed exception would create an incentive for adoption of e-prescribing and EHR technologies of perhaps *two percent* of physicians who would both adopt the new technologies and receive a benefit of up to $3,000 to help defray their costs. (Ibid.).

The CMS-NPRM and OIG-NPRM achieve their negligible effects through a number of provisions that vary only slightly between the two proposed rules:

1. The two proposed rules strictly limit the type of technology to which the exemptions or safe harbors apply.

    - With respect to e-prescribing, they limit the technology to items and services that are necessary and used solely for e-prescribing and that may consist of hardware and connectivity services that are used for more than one function so long as a "substantial use" is for e-prescribing information.
    - With respect to EHR technology, they limit the technology to software that is necessary and used solely for EHR software so long as it has an electronic prescribing component.
    - The "substantial use" provision for e-prescribing is strictly limited to "address the additional risk of abuse provided by multi-functional items and services."
    - Thus, the CMS-NPRM and OIG-NPRM each express concern that donors might provide free or reduced cost software that bundles valuable general office management, billing, scheduling, or other software with the electronic prescribing or EHR features.

2. The CMS-NPRM and OIG-NPRM also limit the physicians or other entities that may receive items and services.

    - When physicians are the recipients, the exceptions or safe harbors, as the case may be, expressly would include donations only to physicians who routinely furnish services at a hospital.
    - The exception and safe harbor thus exclude "remuneration used to induce physicians who already practice at other hospitals to join the medical staff of a different hospital."

3. The CMS-NPRM and OIG-NPRM each state that it would be beneficial to limit the value of donations.

    - The CMS-NPRM solicits comments with respect to e-prescribing on "whether to limit the aggregate fair market value of all items and

The CMS-NPRM and OIG-NPRM each need to be revised substantially so as to allow for the systematic reengineering, outlined above, to take place. Without a clearly defined broad exceptions/safe harbors for the physician self-referral and anti-kickback rules, the cost savings, quality of care improvements, and more appropriate utilization of health care services that health information technologies would promise, will never materialize.

Sincerely,

Anne C. Canfield
Executive Director

CMS-1303-P-18 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Mr. Joel Wakefield **Date & Time:** 12/12/2005

Organization : Coppersmith Gordon

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

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See Attachment

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Coppersmith Gordon Schermer Owens & Nelson PLC
Attorneys and Counselors

December 12, 2005

Delivery via: *http://www.cms.hhs.gov/regulations/ecomments*

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

Re: CMS-1301-P: Comments on Stark Physician Self-Referral Exceptions for Electronic Health Records

To Whom It May Concern:

This letter provides comments on the Centers for Medicare and Medicaid Services' ("CMS") proposed rules on "Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements," 70 Fed. Reg. 59182 (October 11, 2005). We are writing on behalf of health care organizations committed to the implementation of electronic health record (EHR) systems to improve quality and facilitate "a connected system of electronic healthcare information available to all doctors and patients whenever and wherever necessary."[1] The health care organizations sponsoring this comment are Banner Health, Billings Clinic, The Cleveland Clinic Foundation, Intermountain Health Care, Partners HealthCare System, Inc., Scottsdale Healthcare Hospitals, and St. Joseph's Hospital and Medical Center. The American Medical Group Association also supports this comment.

All of these highly regarded health care organizations own or manage hospitals, and almost all employ a large number of physicians. They have all implemented robust EHR systems, including clinical decision support, for their own hospitals and employed physicians. All provide significant specialty physician and hospital services, often attracting patients nationally and internationally, but all concentrate on patients in service areas within several hundred miles of their main clinic and hospital locations. They serve geographic markets from Boston to Billings, serving all kinds of patients, providing all levels of medical services.

[1] Commission on Systemic Interoperability, "Ending the Document Game: Connecting and Transforming Your Healthcare Through Information Technology," at 2 (October 2005) (hereinafter 2005 Commission on Systemic Interoperability Report).

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Within their own organizations, the sponsors of this comment represent the full range of approaches to EHR system adoption. Some have built their own proprietary EHR systems over many years, although they have worked with outside vendors on some aspects or components of their systems. Others, especially those that have adopted sophisticated systems more recently, have worked with one or more EHR vendors. Some combine their own custom programming with vendor-designed EHR. The sponsors of this comment have been at the forefront of EHR adoption and development because they are committed to being at the forefront of delivering high quality health care services. The commitment to quality requires clinically integrated systems operating on the basis of evidence based clinical protocols. The development of EHR systems is a means to an end – coordinated, high quality patient care.

Most of the sponsors have benefited from outstanding physician leadership in their information technology programs, which has been crucial to physician support and successful use of EHR technology to improve care. The sponsors are committed to advancing the patient care benefits of EHR by encouraging non-employed physicians involved in care of shared patients, many of whom are not on their hospital medical staffs, to implement EHR within their own practices.

We know that CMS and OIG are aware of the huge benefits of EHR system adoption and support the goal of removing unnecessarily restrictive regulatory impediments to EHR adoption.[2] We also recognize CMS's statutory obligation not to create exceptions that allow for patient or program abuse. We therefore believe CMS should write more expansive exceptions with the goal of encouraging EHR system adoption, but with conditions or other limitations necessary to prevent patient or program abuse.

As proposed, the EHR rules will seriously impede the development of EHR in ways that cannot be justified by a concern for preventing patient or program abuse. In these comments, we first discuss the need for CMS to clarify what constitutes "remuneration" and how to evaluate "fair market value" in the context of EHR. We then submit comments on the post-interoperability rule and the pre-interoperability rule. We very much appreciate the opportunity to comment on these rules and commend the agency for its careful efforts to craft these regulations.

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[2] 2005 Commission on Systemic Interoperability Report at 2; MedPAC, March 2005 Report to Congress at 219.

I. Clarify "Remuneration" and "Fair Market Value"

The sponsors of this comment want to encourage adoption of EHR systems by physicians on their hospital medical staffs and by physicians who are not on their medical staffs but who share patients with their employed physicians or with physicians on the medical staff. However, with few exceptions, the sponsors are not interested in donating the full value of an EHR system. First, they want outside physicians to be able to access the information in the sponsor's EHR on care received at the sponsor by the outside physicians' patients. For physicians who are on the sponsoring organization's medical staff, this access would include the ability to use the sponsoring organization's EHR for care of the physicians' patients while in the hospital.[3] Second, the sponsors of this comment want to make it possible for these outside physicians to create their own office practice EHR for their own patients (which would in turn be accessible by a hospital that also treats that patient) by becoming "users" of or sublicensing the sponsor's EHR systems at the direct, incremental costs to the sponsor.

The sponsors of this comment already have taken the first step toward giving outside physicians access to information on their patients within the sponsors' EHR systems. Based in part upon previous CMS guidance, they do not believe that giving "read only" access to physicians is "remuneration;" nor do they believe that allowing physicians on their medical staffs "read and write" access to order tests and medications or to view and enter additional information into patient records (even from their offices) is remuneration.[4] While these widely shared assumptions have allowed the expansion of the use of EHR, CMS should state clearly that read and write access to a hospital EHR system is not remuneration. In addition, CMS should state that it is not remuneration to

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[3] This first step does not include providing an EHR platform for that physician to develop his or her own EHR for an office practice.

[4] CMS confirmed in the preamble to the 2004 Phase II regulations that remuneration does not include an entity's provision to a physician of computer or other technology solely intended to convey information by a physician to that entity. 69 Fed. Reg. 16054, 16113 (March 26, 2004). See also 42 U.S.C § 1395nn(h)(1); 42 C.F.R. §411.351 (definition of remuneration does not include the furnishing or items that are used solely to collect, transport, process or store specimens for the entity furnishing the items, or solely to order or communicate test results or procedures.). For some organizations, because technology access is not given to "all members of the medical staff" for legitimate reasons having nothing to do with referrals, it is important that "read and write access" by medical staff members that allows them to take care of their patients and electronically sign records is a basic operational function that benefits the hospital and its patients and is not considered to be "remuneration," rather than trying to make the access fit into the exception for "incidental medical staff benefits." 42 C.F.R § 411.357(m). Health care entities understand that giving multi-functional hardware or connectivity services to outside physicians would constitute remuneration under the Stark law.

give physicians access to clinical protocols and electronic medical libraries,[5] even if doing so provides an incidental benefit to the physicians' patients who are not shared.[6]

Second, the sponsors of this comment want to allow outside physicians to take advantage of the pricing the sponsors can make available at their direct, incremental costs for EHR technology and support services, which would enable the outside physicians to create their own office EHR for their own patients. In our experience, a common practice is for larger health care organizations to function as purchasers of EHR systems for smaller "users,"[7] with the EHR vendors knowing that the larger health care organizations will pass through the direct, incremental costs of providing an office practice EHR for the outside physician practices as the "fair market value" price.[8] 42 U.S.C. §1395nn(e)(8) permits the provision of items and services to physicians "at a price that is consistent with fair market value." CMS should clarify that the "fair market value" standard is satisfied when larger health care organizations price EHR systems, components of systems, or technical support services for additional users, including outside physicians and their practices, on the basis of the organization's direct, incremental costs. *See* 42 U.S.C. § 1395nn(h); 42 C.F.R. § 1001.952. This, in and of itself, will make a substantial contribution to the ability of larger health care organizations to encourage adoption of EHR systems by physicians in small practices.

II. Post-Interoperability Electronic Health Record Exception: § 411.357(x)

We begin by commenting on the post-interoperability exception because it offers the best opportunity to address the elements that should be in the final Stark physician self-referral exception for EHR in the long run. As discussed in Section III, we believe the pre-interoperability rule should be consistent with the post-interoperability rule with the changes we recommend below. Further, we urge CMS to publish the post-interoperability rule at the same time as the pre-interoperability rule, even if the final interoperability standards have not yet been adopted. Organizations are likely to take a "wait and see" approach to donations until the post-interoperability rules are published.

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[5] JCAHO requires hospitals to provide "knowledge-based information services" by which they mean libraries, "in any of the following forms: print, electronic, internet, or audio." JCAHO requires "after hours access" by "electronic means." See Standard IM. 5.10, *Comprehensive Accreditation Manual for Hospitals*, Update 3, August 2005, at IM-11-12.

[6] As a practical matter, it is not reasonable to give outside physicians access to clinical protocols and a electronic medical library for use on shared patients and expect them not to use it for their other patients.

[7] The organizations sponsoring this comment have negotiated the right to either add outside physicians as additional "users" or to sublicense use of the system at an additional cost, unless, of course, they have built their own proprietary systems and, therefore, are free to grant EHR access and use without worrying about licensure issues with vendors.

[8] The EHR vendor market includes vendors who specialize on working with smaller physician practices directly and vendors who work with larger EHR user systems and access smaller physician practices by adding the smaller practices as "users" for a fee or as sublicensees.

A. Covered Technology

It is vitally important that any new rule provide for a broad definition of electronic health records and a wide array of uses of electronic health record systems. The proposed EHR rule language is too narrow to encourage the known benefits of EHR adoption in physician offices as characterized by the Commission on Systemic Interoperability, Institute of Medicine, and the Medicare Payment Advisory Commission (MedPAC).[9] The proposed rule limits protection to "[n]on-monetary remuneration (consisting of items and services in the form of software or directly related training services) necessary to receive, transmit, and maintain electronic health records" under specified conditions.

1. Adopt a Broad Definition of the Protected EHR System

Determining what is included in the protected EHR is fundamental to the ability of potential donors to safely donate, especially because of CMS's concerns about improper subsidies of administrative systems that are extraneous to the EHR. In our view, the protected EHR should be defined broadly to cover far more than the mere medical record in electronic format.

CMS has asked for comments on the definition of "electronic health records." 70 Fed. Reg. at 59188. We believe the definition should be designed to accomplish at least two well-established objectives of EHR systems.[10] First, it should promote "a connected system of electronic healthcare information available to all doctors and patients whenever and wherever necessary."[11] Full information exchange among providers reduces errors and improves quality. Second, EHR systems should be a tool for collection of quality and outcomes measures to facilitate pay-for-performance payment methodologies. CMS is a major proponent of such measures, so we will not describe them further in this comment.

In discussing "covered technology," CMS has expressed its intent to protect "integrated packages that could positively impact patient care," while avoiding protection of administrative software that does not also further the goal of improving patient care.

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[9] 2005 Commission on Systemic Interoperability, supra; Institute of Medicine, *Crossing the Quality Chasm* (2001) and *Quality Through Collaboration: The Future of Rural Health* (November 2004); MedPAC, March 2005 Report to Congress, Chapter 4, "Strategies to improve care: Pay for performance and information technology. See also research on how EHR is actually used in small physician offices. R. Miller, et al, "The Value of Electronic Health Records in Solo or Small Group Practices," 24 Health Affairs 1127 (September/October 2005).

[10] We would also like for CMS to consider a third objective – protecting the privacy and security of EHR systems. If this were added as a goal, then EHR systems, as defined in these rules, would also include auditing and security functionality to prevent and detect privacy breaches. Auditing software is often a separate add-on component of an EHR system. Although EHR software is typically designed to capture the information needed for an audit, getting that information out of the EHR system often requires purchase of separate auditing software or special programming.

[11] 2005 Commission on Systemic Interoperability Report, at 11 Executive Summary. See also MedPAC, March 2005 Report to Congress.

70 Fed. Reg. 59188 and 59190. Consistent with CMS's intention, MedPAC in its March 2005 Report to Congress explicitly embraced EHR as a valuable tool in achieving the two objectives above – promoting connectivity to achieve quality and measuring outcomes – and made a distinction between EHR clinical information technology systems and other "administrative systems." MedPAC describes an EHR "clinical information technology" (IT) system as follows:

> Clinical IT comprises multiple applications that support different functions in health care, such as:
> - tracking patients' care over time (the electronic health record);
> - allowing physicians to order medications, lab work, and other tests electronically, and then access test results (computerized provider order entry);
> - providing alerts and reminders for physicians (clinical decision support systems); and
> - producing and transmitting prescriptions electronically (e-prescribing).[12]

All of these functions, not just the first narrow view of EHR as a method of "tracking patients' care over time," should be protected by CMS in the EHR exception (whether CMS regards the functions as mandatory or optional).

MedPAC also discusses specific "functions" and "outcomes" of clinical information technology, especially important for allowing measures of quality and outcomes. The "functions" include: registry for patients with chronic conditions; registry for all patients; system for tracking patients after an acute event to determine follow-up; system for tracking test results and prompting follow-up of abnormal tests; medication safety checks (allergies, dose, age, drug-to-drug interactions); system for decision support within the patient encounter; system for tracking lab results, including status of patient notification; and system for aggregating, measuring, and monitoring patients by category, such as disease, medications or age.[13] The "outcomes" of clinical information technology identified by MedPAC include: patients with chronic conditions tracked and sent reminders prompting office visits or other necessary follow-up; patients in the practice screened for risk factors; patients who are identified as at-risk are contacted; patients with potential drug-to-drug interactions are contacted; patients are contacted to communicate lab results; and quality measured internally and care management improved.[14]

We recommend that the definition of EHR used in the CMS exception be at least as encompassing as the MedPAC definition of clinical information technology, and that CMS articulate a presumption that software falls into the protected definition of EHR if it

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[12] MedPAC 2005 Report to Congress at 206.
[13] MedPAC 2005 Report to Congress at 198.
[14] MedPAC 2005 Report to Congress at 198.

is designed, marketed, or reasonably used in a way that substantially fits any element of that definition. Further, CMS should state that software designed primarily to further the functions and outcomes of EHR described by MedPAC (or other similar functions and outcomes as the technology develops) is deemed to meet the definition of protected EHR.

If the "outcomes" MedPAC identified above are deemed to fall into the definition of EHR, a "patient portal" that includes communicating with patients about the full range of clinical issues, such as scheduling, appointment reminders, and alerts, will be protected. In addition, as the Commission on Systemic Interoperability has pointed out, the ability of patients to electronically access their own EHR information, such as results of lab tests, will become increasingly important to improving patient care. Patient portal software is designed to facilitate a broad range of patient communications. Therefore, we recommend that CMS include patient portal software, including a scheduling function, in the definition of protected EHR.[15]

We also believe that the CMS exception should extend to donations of any element, component, or function of an EHR system, because building an EHR system incrementally over time makes sense. That is, in fact, how most of the organizations sponsoring this comment have built their own EHR systems. Donors should be able to donate an element of an EHR system or special programming to support a particular patient care goal, such as a specific clinical protocol that can be added to an existing EHR system.

CMS should not require that a donation have all of the elements CMS regards as "core" to an EHR. For instance, the organizations sponsoring this comment strongly believe in computerized provider order entry (CPOE), and believe it must be included in any definition of a protected EHR system; however, we do not believe that donations should be *required* to include CPOE to be protected. Similarly, while we strongly believe that providing access to an electronic medical library should fall into the definition of a protected EHR system because it is part of clinical decision support,[16] we would certainly not argue that it must be included in order for the donation to be protected, although we believe donors should be allowed to donate it as an addition to an existing EHR system. Trying to force broader EHR system adoption by only protecting EHR donations that include defined "core" elements is likely to have the unintended consequence of discouraging donations of important components of a system.

While the sponsors of this comment support an expansive definition of EHR, we do not believe that the protected software must include certain types of clearly separable administrative software (e.g. billing, coding, or practice management software), except software, such as the patient portal, that is related to communications with patients,

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[15] The importance of a broad definition of EHR that includes patient communications is also emphasized in the 2005 Report by the Commission on Systemic Interoperability.

[16] For a discussion of the important of electronic medical libraries, especially to generalist physicians in rural areas, see The Institute of Medicine, Quality Through Collaboration: The Future of Rural Health, at 155 (2004).

including scheduling and reminders. However, we urge CMS to make it clear that elements of an EHR system that incidentally facilitate administrative functions will not remove it from the protection of the rule. For instance, EHR systems have links to diagnosis codes used by physicians to describe patient care and to engage in order entry, as well as supporting coding and billing administrative software. EHR systems are increasingly able to identify whether a service is considered "medically necessary" by Medicare, which is useful both clinically and administratively, allowing the EHR to generate advanced beneficiary notices (ABNs) that support billing. The elements of an EHR that support administrative functions, as well as patient care functions, are highly valued by physicians; indeed, these dual use functions are often a major reason physicians begin to use an EHR. Not only is it practically impossible for donors to remove such functionality from EHR system donations because of how the software is designed, but it would reduce the use of these systems by physicians, and, therefore, the benefits to patients. So while we believe CMS must allow certain administrative features to be included within the definition of protected EHR software, we agree that administrative software that is not integrated into the clinical EHR does not need to be protected.

2. Include Technical Support

One major reason for slow EHR adoption by physicians is lack of available technical support to acquire and maintain an EHR system.[17] Painful and expensive experience with installation of software over the past decade has demonstrated that reliable technical support is essential to successful implementation and ongoing maintenance of any software system. All of the sponsors of this letter have built substantial internal IT support services. None of the sponsors of this comment would have considered implementing an EHR system without having in place both reliable internal technical support (often called the "help desk') to address routine questions and diagnose problems, as well as outside technical support to solve problems internal IT staff cannot solve and to provide ongoing updates and upgrades to the system.

As a practical matter, EHR software must interface with administrative software, and technical support will be required to make those interfaces work. Organizations that adopt EHR systems will have previously begun the journey toward electronic systems with some kind of administrative software (given Medicare requirements, they probably started with electronic billing software), and that software will need to interface with the EHR software.[18] To avoid repeated collection of demographic and payor information from patients, interfaces with the billing and practice management software must be

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[17] MedPAC March 2005 Report to Congress at 207, 212. "Few providers, and especially those in smaller settings, know enough to navigate a large and complex market of IT products, implement their choice, and maintain a system over time. . . . These difficulties have led to implementation failures."

[18] See R. Miller et al, supra, at 1129, indicating that EHR systems in small physician practices interface with billing.

developed. Coding software, designed to support coding and reduce mistakes, also should interface with EHR software.[19]

Donations of technical support should be protected, even if not accompanied by donations of EHR software, as long as the technical support is connected to the acquisition or use of an EHR system. This will reduce the likelihood of program abuse by allowing donations of EHR technical support to physicians who want to evaluate how an existing EHR system can better communicate with other EHR systems. For instance, if a physician received some of his EHR system from one vendor or donor and wants to know how it can be made to communicate with another system, the other system should be able to donate technical support to make that assessment. Doing so will promote interoperability and connectedness, and reduce the ability of any single donor of EHR to work exclusively with a physician. Donations of technical support will also promote connecting different EHR systems into community health information networks, as they develop. Furthermore, the Department has made the EHR software used by the Veteran's Administration, VistA, available to all physicians, for free. Physicians in small practices may find this attractive, but only if they receive technical support to evaluate the appropriateness of the software for their practices, to install it, and to maintain it over time. Donors should be allowed to donate technical support of EHR software, including interfaces to administrative software and connections to other EHR systems, even when they do not donate that software themselves.[20] Without such protection, many EHR systems will not be properly installed or maintained in physicians' offices, both negating the benefits of the system and souring many physicians' perceptions of the benefits of EHR.

We therefore urge CMS to write an exception that allows donations of technical support at all stages of EHR acquisition, implementation, and maintenance, including support of the interfaces to related administrative software and connections between EHR systems. Furthermore, as discussed below, because of the difficulty of valuing technical support and because such donations will not lead to program abuse under the conditions recommended in this comment, we recommend that it be removed from any cap CMS might consider and from any obligation to "value" donated EHR-related services.

3. Remove the Requirement that Donations Be "Necessary"

Even if CMS adopts a more expansive definition of EHR, it should remove the limitation implicit in requiring that the donation be "necessary" to receive, transmit, or

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[19] The DHHS Office of National Coordinator for Health Information Technology, working with AHIMA, has initiated programs that would use information technology to reduce Medicare fraud. See http://www.hhs.gov/healthit/hithca.html. In addition, we urge CMS to recognize that some coding functionality must be built into and protected as part of the EHR software in order to facilitate an effective interface to separate coding administrative software.

[20] One obvious place where technical support will be crucial is in making the upgrades to interoperability. Any organization should be able to donate IT staff to help make its system interoperable with other providers' systems.

maintain EHR. While CMS does not discuss "necessary" within the context of the EHR exception, it states that it has the same meaning as "necessary" in the e-prescribing regulation. 70 Fed. Reg. at 59184-85. There, the term is mainly discussed with regard to e-prescribing hardware, specifically a hand-held device capable of transmitting electronic e-prescribing information, and the word "necessary" is used to prevent duplicative donations of "technically or functionally equivalent" hardware.

In the context of the EHR exception, which, if the recommendations in this comment were adopted, would apply only to EHR software, training, and technical support, there is no hardware equivalent to which the term "necessary" would apply. We do not know of a reasonable way to evaluate whether software, training and technical support is "necessary" or "technically or functionally equivalent" to anything the recipient possesses.[21] Would this require a donor to determine, for each and every potential recipient, if a higher quality EHR related donation is really "necessary" if a lower quality one might do? When a requirement is difficult to determine and carries substantial penalties for mistakes, lawyers will recommend hiring expensive outside experts,[22] diverting scarce resources from beneficial EHR donations and into documentation and certification efforts. Indeed, the potential for confusion, uncertainty, and perceived legal risk may be higher in this section than any other in the proposed rule. Moreover, we fail to see how either the word "necessary" or the related certification requirement prevents program abuse, as long as the donation is connected to legitimate EHR functions.

Dropping the word "necessary" from the language of this section would break the connection to the e-prescribing rule's use of the term and to the certification requirement that donated technology not be "technically or functionally equivalent" to what the physician possesses at the time of the donation. We recommend replacing "necessary" with the less restrictive phrase "used in connection with."[23] It would also eliminate the need to determine if donated EHR software is "necessary" if free software, such as the VistA software, is "technically and functionally equivalent." The "used in connection with" language sufficiently limits the donation to EHR functionality, without allowing donations that support other aspects of a physician's professional or personal activities.

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[21] Vendor EHR software is packaged with components that owners can turn off or on when they need that component. Therefore, it's possible that donated software will have a component that no one intends to use, but is built into the system and may be "technically or functionally equivalent" to something the recipient already has.

[22] If the certification standard remains, CMS should allow monetary donations to pay for certification experts.

[23] This phrase comes from the CMS discussion of the purpose for the word "necessary" in the e-prescribing reg. 70 Fed. Reg. at 59184.

4. Clarify That the Limitation to "Nonmonetary" Donations Allows Payment for Licenses and Users' Fees

In many cases donors will make EHR systems available to outside physicians by paying a user's fee or licensing fee to the vendor of the donor's EHR system, in accordance with the contract between the donor and the EHR vendor. CMS needs to make it clear that this payment, because it is necessary to the donation of the EHR, is protected by the CMS EHR exception. CMS also needs to make it clear that the outside physician and the donor system can split this fee (on some basis unrelated to the volume or value of referrals), which would effectively allow the donor to subsidize the physician's acquisition of the EHR system, without covering the full costs. Furthermore, consistent with the discussion below of permissible recipients, the donor system should be allowed to give all of the physicians in a targeted physician's group, employer, or network (who tend to share coverage and call) the ability to be added as users by payment of the user's fee or license fee, whether or not the donor chooses to subsidize some part of the fee.[24]

B. Permissible Donors

In this section, we urge CMS to permit any entity subject to the Stark law to donate to physicians—even those that are not on the "medical staff" of hospitals or members of group practices—as long as three conditions are met: (1) the donor and physicians share care of patients, (2) the donor has a legitimate reason for making the donation that is not "directly related to" the volume or value of referral services, and (3) the donation otherwise complies with reasonable conditions.

CMS should explicitly allow a donor "entity" subject to Stark to use a separate, but related organization, such as a Management Services Organization (MSO) or an independent practice association (IPA), as a vehicle for donations protected by this rule.[25] In addition, there is no reason to exclude post-acute facilities (nursing homes and home health agencies), laboratories or ambulatory surgery centers, each of which may have a special component of an EHR that may be especially useful in improving patient care in their area of expertise, as long as the donation is related to care of shared patients. Indeed, allowing more potential donors may actually **reduce** the risk of program abuse.

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[24] Please see the discussion in the "preliminary comments" in Section I, requesting that CMS state that a large system may make its EHR system available to outside physicians for use in their offices by passing through a users fee or licensing fee, and that doing so is considered "fair market value."

[25] The MSO or IPA itself may not be an "entity," as defined by Stark, but, through it, the sponsoring organization, which is an "entity," will have an indirect compensation arrangement with physicians. Donations through the MSO by the entity should be protected by this rule.

C. Permissible Recipients and the Selection of Recipients

As currently written, the rules allow hospitals to donate only to members of the medical staff who "routinely furnish services at the hospital,"[26] group practices to give to their own employees and members, and prescription drug plan (PDP) sponsors and Medicare Advantage (MA) organizations to give to physicians. On this point the rule is unnecessarily narrow and fundamentally contrary to the goal of connecting all physicians and other providers to health care information whenever and wherever needed.

Given the policy objective of encouraging rapid adoption of EHR systems that connect all physicians and patients in all practice settings to all relevant clinical information, the exception should allow any entity subject to the Stark law to donate to physicians—even those who are not on the "medical staff" of the donor's hospitals or members of group practices—as long as the three conditions previously mentioned are met, *i.e.* donor and physicians share care of patients, the donor has a legitimate reason for making the donation that is not "directly related to" the volume or value of referral services, and the donation otherwise complies with reasonable conditions.

As potential hospital donors, we believe limiting permissible recipients to members of the medical staff is far too narrow and will leave many of the patients we serve without a way of including all of their health information into an interoperable EHR. All of the sponsors of this comment have a large number of employed physicians or physicians on the medical staff who regularly provide consulting and care to patients who use physicians who are not on the medical staff.[27] EHR is another tool for taking care of patients, and it should naturally develop among physicians who share patients. As a practical matter, physicians are more likely to adopt EHR if they can work with the larger systems they already rely upon for specialized care of patients. We also believe that group practices should be able to donate to physicians who are not members, employees or independent contractors, under the same criteria that should apply to hospitals.

By widening the range of permissible recipients to include physicians who are not on the medical staff of the donor hospital, CMS will more effectively promote true interoperability and improve the quality of care that comes from physicians and patients being connected to health information whenever and wherever needed than by any other change in the proposed rules. This is because these physicians, by definition, have their primary hospital affiliation with another hospital, and consequently will want the donor's

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[26] The quoted language comes from CMS's discussion of the e-prescribing rule, which, we assume, would also apply to the EHR exceptions.

[27] Several sponsors of this comment routinely provide subspecialty care and consulting to patients in rural areas. The primary care physicians of those patients are not likely to be on the medical staff of a hospital that has EHR or is in a position to donate. When one considers that EHR adoption in rural areas lags behind the slow adoption by physicians in urban areas, this failure of the proposed rule to allow donations by large organizations to rural physicians with whom they regularly share patients is especially troubling. See generally IOM, *Quality Through Collaboration: The Future of Rural Health* (November 2004).

EHR system to be interoperable with the system that is developed at their primary hospital.

Given the purposes behind EHR adoption, the comment sponsors hope to use the CMS EHR exception to target donations, incrementally and over time, as technology develops and budgets allow, to maximize the benefit of the donations around legitimate objectives. Donations would consider a number of objectives, including connecting physicians with whom we share the most patients (thus maximizing the benefits of EHR to the largest number of patients); connecting physicians who treat specific diseases or have medical concerns[28] we have targeted for improvement through use of EHR; connecting physicians who work together to achieve quality outcomes or pay for performance objectives that would be advanced by use of a common EHR; and connecting our physicians and facilities with "safety net" providers who often serve the uninsured and do not have the resources to adopt an EHR without help. We believe we can achieve these objectives under the language in the proposed post-interoperability exception that allows donations if "neither 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," but only if "directly related to" is interpreted to allow donations to achieve the legitimate objectives identified above.

We support CMS "deeming" certain conduct to be permissible under the "directly related to" standard, and are especially supportive of the "deemed" standard allowing donations if the "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." § 411.357(x)(4)(vi). However, we are concerned that the conduct "deemed" acceptable be broad enough to allow the proper identification of potential recipients, such as on the basis of the factors suggested above.

It is absolutely vital to a donor's ability to donate to be able to distinguish between allowable donations (even those indirectly related to or correlated with referrals), from impermissible donations (those "directly related to" referrals). For instance, organizations with a reputation for treating heart disease or that have agreed to measure outcomes related to heart disease may want to target EHR donations to primary care physicians who routinely consult with the cardiologists employed by the donor, even if the primary care physicians do not have medical staff privileges at the same hospital as the cardiologists. After all, cardiologists need to know about the primary care received by their heart patients and need to have those primary care physicians follow clinical protocols, which are built into EHR systems. The fact that the treatment of heart disease, by its nature, involves substantial referrals of designated health services should not make

[28] An example of a medical concern would be controlling post-operative infections by improving both pre-operative and post-operative patient care, which means that outside physicians must be connected with the surgeons.

that donation suspect. To the contrary, it should be welcomed as a way to improve care and reduce hospitalization of heart patients.

Therefore, we strongly urge CMS to recognize that permissible potential recipients of donations include any physician (not only those on the medical staff), as long as the donor consistently applies criteria for establishing eligibility for a donation based upon legitimate business and clinical considerations not directly related to the volume or value or referral services or to a strategy of shifting referrals. CMS should then deem that the following considerations are allowed in choosing recipients:

1. Physicians within a defined geographic area who have historically shared a minimum number of patients with the donor, the donor's employed physicians or clinicians, or physicians on the donor's medical staff;

2. Physicians within a defined geographic area who have historically shared a minimum number of patients who have a particular disease or medical concern with the donor, if the donor is donating software or services that will improve the care of the physicians' patients with that disease or concern;

3. Physicians in a health plan network of which the donor is also a participant or who are otherwise involved in a program to measure outcomes with the donor (such as a CMS pay for performance demonstration program), if the physician has agreed to outcomes or pay for performance measures that would be advanced by use of an EHR system; and

4. Physicians within a defined geographic area who can demonstrate that they serve a large underserved patient population and can meet financial need criteria established by the donor, whether or not the donor and physicians share a specified number of patients.

In applying the above criteria for identifying permissible recipients, the following must be allowed if donors are going to be able to reasonably control their operations and respond to unexpected circumstances:

1. If identifying a minimum number of shared patients is required, as suggested above, the donor (rather than CMS by rule) should be able to specify that number; otherwise the donor cannot reasonably adjust that number to remain within its budget.

2. The donation should be allowed to be given not only to individual physicians, but also to the physicians' group or employer (because if a physician is in a group or employed by a health care entity, he or she will acquire EHR through the group or employer) or any network or IPA the physician may be using to acquire EHR. If the donation is given to the physician's group or employer, everyone in the group

involved in care of shared patients should be allowed to use the donated technology and services.[29]

3. The donor should be allowed to decide not to give a donation if it determines a physician, physician group, physician employer, or physician network should be excluded on some legitimate criteria,[30] even if it means that individual physicians who otherwise meet the criteria for receiving a donation are excluded.

4. The donor should be allowed to suspend donations or change criteria for making donations at any time to address unforeseen business and clinical concerns, developing technology, technical support problems, the need to comply with government regulations, and other legitimate considerations not directly related to selection of recipients based on the volume or value of referral services.

D. Value of Protected Donations

We urge CMS not to cap EHR donations. As potential donors, it is quite clear that the other requirements of this proposed rule and sheer economic reality will prevent excessively large donations that raise a realistic likelihood of program abuse, especially given the Stark incorporation of the anti-kickback statute, which would punish unusually large donations intended to induce referrals. The sponsoring organizations do not expect to make large donations to individual physicians or their practices.[31] Thus, while a cap may actually be in the economic best interests of potential donors, we oppose such a measure because it is expensive and difficult to track, especially under a strict liability law where harmless mistakes (such as the failure to correctly identify the donation or to correctly calculate or document its value) create substantial penalties.

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[29] We urge CMS to specifically address how donors can make donations to a physician's employer, group practice, or network. For instance, if a physician in a group is eligible to become a "user" under eligibility criteria established by the donor, then all of the physicians who share care of patients within the group also need to be "users" as a practical matter. If the way a donor makes someone a "user" is by adding him to the license it has negotiated with a vendor, then the donor should be allowed to add all of the physicians in the group as users, upon payment by the group of the direct, incremental costs of the donor. If these direct, incremental costs are considered a fair market value payment, then existing law would allow it. This is, therefore, one of those areas in which clarification of "fair market value" by CMS would be enormously helpful.

[30] The legitimate reasons for not making a donation to an otherwise eligible physician might include: the physician has no real interest or need, which might lead the donor to expect the physician would not use the donation (e.g. imminent retirement) or the potential recipient already has or is planning to acquire elements of an EHR system, even if not functionally equivalent to the software or services being donated.

[31] For instance, given existing internal methods of identifying costs and budgeting, none anticipates donating more than a total of $35,000 per physician, and most expect to spend far less than that, more in the range of up to $5,000. This number, however, would be dramatically impacted by the items or services the donor is required to value under the cap. One of the reasons we oppose the cap is the difficulty of foreseeing the future value of everything that is necessary to make EHR effective that might be included under the cap.

If CMS and OIG believe a cap is necessary to prevent program abuse, we encourage that application of the cap be limited to the anti-kickback safe harbors. An alternative to the cap might be to suggest that relatively large donations targeted on high volume referral sources may be subject to special scrutiny to determine if the donations otherwise meet the requirements of the Stark EHR exception.

If CMS believes a cap is necessary under the Stark exception, we urge CMS to remove from the cap EHR related donations that are not likely to be abused or are difficult to value prospectively. Based on substantial experience, we know that physicians do not enjoy spending extra time on either training or technical support. They want to know how the EHR system works (therefore they want training for themselves and their staff) and they want the system to work as it is suppose to work (therefore they want reliable, timely technical support). They do not want trainers or technical support staff hanging around unnecessarily. These functions are, therefore, by their nature not subject to abuse. CMS can effectively deal with inappropriate use of the donor's training and support staff by imposing a condition that donations be connected to EHR functions, and not to other office or personal matters. Indeed, we believe the "used in connection with" language suggested above (as a replacement for "necessary') would create a link between donated services and EHR related functions.

Donations of updates and upgrades should be excluded from any cap because they are difficult to prospectively value and occur often to bring the EHR into compliance with new laws and regulations or to introduce or improve evidence-based clinical protocols and alerts. We expect that interoperability will require constant updates and upgrades over time in EHR systems.[32] CMS should encourage constant improvement in EHR systems. Imposing a burdensome requirement of valuing and documenting such donations will reduce innovation and improvement. Furthermore, it is difficult to see program abuse resulting from this kind of donation.

CMS should not cap donations to "safety net" providers, as described above, including physicians in nonprofit and governmental entities that meet some standards of community service and financial need.

Finally, to the extent CMS believes a cap is necessary, it should give donors the maximum flexibility to address any cap requirement. Donors should be able to limit donations to a certain amount per physician or to a percentage of the value of the donation subject to the cap, in their discretion. The cap should be a life-time cap, rather

[32] Other examples are numerous. If CMS includes privacy and security features into its definition of protected EHR software, which we advocate, then improvements in auditing and encryption software should occur. CMS constantly changes diagnosis codes and standards of medical necessity that are built into EHR systems. CMS is likely to encourage use of coding and billing software to improve operational efficiency and reduce mistakes, and since CMS constantly changes the coding and billing rules, updates and upgrades are necessary, including testing and improving the interfaces of those systems with the EHR system. CMS should not burden these kinds of improvements by subjecting them to a cap, and valuation and documentation standards.

than constrained into a short number of years, and it should be an aggregate cap, rather than an annual cap. CMS should accept any reasonable, objective methodology to value services under the cap, including approximations.

E. Certification and Documentation Requirements

For reasons discussed above (*see* Section II.A.3.), we oppose the certification requirement in §411.357(x)(5) and (6) that would prevent donation of items or services that are "technically or functionally equivalent" to those already possessed by the physician. As explained in more detail in the prior section, this requirement is neither necessary to prevent program abuse nor realistic as a practical matter when applied to donations of EHR software, training, and technical support. If required at all, it should be in the context of the anti-kickback safe harbor where a technical failure to satisfy this requirement does not automatically trigger penalties.

With regard to the documentation standards in § 411.357(x)(5)(i)(ii) and (iii), while we recognize that it is consistent with other Stark exceptions to require a writing signed by the parties, specifying covered items or services and the value of those items or services, and covering all such services, we do not believe the same stringent documentation standards should apply in the very complex context of EHR. In particular, we urge that CMS drop the requirement documenting the "value" of the donated items and services, especially the training and technical support, for the reasons suggested above in the discussion in Section II.A.3. of the cap and the value of the donated items and services.[33] If documentation of "value" is required at all, it should be in the context of the anti-kickback safe harbor where a technical failure to satisfy this requirement does not automatically trigger penalties.

We also request that CMS not require that the writing specify in detail donated software, training, and technical support because of the difficulty—amounting to near impossibility—of doing so when much of what will be needed will occur after the initial donation and documentation. If required at all, such a requirement should be in the context of the anti-kickback safe harbor, where a technical failure to satisfy the requirement does not automatically trigger penalties. However, if CMS requires documentation specifying the items or services being donated, it should require only a general statement that the donor will provide training and technical support connected to EHR, in accordance with internal guidelines, and should not require valuation of training

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[33] As discussed earlier in this comment (*See* Section I), we would encourage CMS to explain what it means by "value," which we assume means the same as "fair market value," in this context, in order to promote the ability of organizations to use the existing exception in Sec. 1877(e)(8) for the purchase of items and services by a physician from an entity. We note that that requirement in the statute does not require a written agreement, as long as the payments are at "fair market value." The absence of burdensome documentation requirements make this attractive, but only if CMS draws a line between what is and is not remuneration in the context of EHR and describes reasonable methodologies for determining fair market value, including a pass-through of the organization's direct, incremental costs.

and technical support.[34] With regard to software donations, it should define updates and upgrades as covered by the initial donation, without requiring additional documentation, even if subsequent upgrades are discretionary and require payment of an additional fee.[35] Only donations of new software (not updates and upgrades of existing software) should need to be documented, and it should be acceptable for that to be done by an addendum or in any other reasonable manner, including e-mail communication between the donor and recipient.

III. Pre-Interoperability EHR Exception, § 411.357(w)

Our primary concern with the pre-interoperability rule is that its narrow scope will deter organizations, including the sponsors of this comment, from promoting EHR adoption until after the post-interoperability rules have been finalized. The pre-interoperability rule should not differ in substance from the post-interoperability rule, except in a few ways targeted at promoting interoperability, connectivity, and interface development between different EHR systems during the pre-interoperability period.

A narrower pre-interoperability exception cannot be justified based upon a reasonable concern with program or patient abuse, especially given reasonable conditions that promote ongoing efforts toward interoperability. For two reasons, we believe CMS's concerns about pre-interoperability program abuse related to the creation of "stand-alone electronic health records systems"[36] is based upon an inaccurate understanding of current developments in EHR systems and markets, as explained below.

First, interoperability is a process. Even now, as EHR software systems are being built piece by piece and updated constantly, organizations are continually working to create interfaces and connections that allow electronic communications about patients. The interfaces and connections are both within the EHR system—allowing, for instance, a hospital EHR system to access the lab system and the clinic records—and between the EHR system and administrative systems, such as billing and coding. Organizations also are actively working with vendors and other health care organizations on creating health information networks and on direct connections between different systems' EHR. Once

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[34] If it does require valuation of training and support services, it should specify that valuing the approximate direct costs of staff time suffices and that unexpected needs for training and support, even if not documented, will not violate this documentation requirement.

[35] It is, for instance, very likely that many EHR vendors will treat bringing their systems into compliance with interoperability standards as an upgrade, with a fee. The owner/licensee of the EHR system should be able to pay that fee without having to apportion the value of that upgrade to all outside recipients of donated software and without having to change the documentation related to donations.

[36] CMS writes at the beginning of the post-interoperability discussion: "We realize that variable (that is non-standardized) adoption of electronic health records systems could discourage market forces and competition from improving healthcare. Interoperability could mitigate many of our concerns regarding the potential anti-competitive effects of stand-alone electronic health records. We recognize that stand-alone electronic health records systems, even if widely adopted, may not deliver the error reductions, cost savings or marketplace changes necessary to meet the Secretary's goals, and could even shift the market toward more fragmentation." 70 Fed. Reg. at 59189-90.

physicians are accustomed to EHR and the benefits for their patients, they push to obtain electronic access to records as they or their patients move between facilities and different EHR systems. While CMS envisions the regulatory step from pre-to-post interoperability as a huge step, for EHR system vendors and owners that step will be simply the next step of an extended process they have been engaged in for quite some time.

Second, CMS suggests that some donors might see a market advantage to "stand-alone" EHR systems that would be anti-competitive.[37] We see none of this; indeed, we see that "stand-alone" systems are not favored in the market and will not last long in light of ongoing efforts to develop interoperability standards. Indeed, the path to interoperability and away from "stand alone" systems already exists in contracts. For years, purchasers of EHR systems have insisted upon and received contractual assurances that their systems will be updated or upgraded to meet federal standards as they are promulgated.[38] EHR systems (or, more likely, components of systems) that do not update or upgrade to meet interoperability standards will quickly become obsolete and will be replaced by others that meet those standards. Stand-alone systems will simply not continue to be supported post-interoperability based on any kind of perceived market advantage related to forcing referrals within the system. Physicians will not tolerate that kind of closed system once alternatives are available, because it is detrimental to patient care and is inconvenient. All of the sponsors of this comment, whether they have their own proprietary system or a vendor system, expect to meet interoperability standards in order to continue to have a system that is connected, rather than isolated.

Unfortunately, a narrow pre-interoperability proposed rule will seriously delay EHR adoption by causing donors, like the sponsors of this comment, to take a "wait-and-see" attitude until the post-interoperability rules are in effect. The sponsors of this comment are poised right now to begin EHR donations consistent with the comments in the post-interoperability discussion above. In some cases, donations were budgeted to begin in the first or second quarter of 2006. However, the sponsors of this comment would have serious difficulty making donations under the pre-interoperability rule, as proposed.

While CMS has stated that it expects interoperability standards to be adopted by the Secretary by the third quarter of 2006, we are concerned that this time frame may be optimistic. Furthermore, CMS has stated that it will not finalize post-interoperability rules until after the Secretary has adopted interoperability standards. 70 Fed. Reg. at

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[37] See quote in previous footnote. We question whether the concern with the anticompetitive nature of stand-alone systems falls within CMS's authority to address program and patient abuse. We also encourage CMS to contact either the Federal Trade Commission or DOJ's Antitrust Division with regard to its competitive analysis and concerns.

[38] Often the contract language in question requires that the software meet federal law and regulation, and makes that an ongoing obligation of the vendor, as long as the vendor provides support. That language has been effective in requiring vendors to create systems that can meet HIPAA privacy and security standards, as well as being able to send standardized bills electronically. Meeting interoperability standards will simply be another set of regulations requiring new programming or interfaces.

59190. That means that even if interoperability standards are promulgated by the third quarter of 2006, it is likely to be 2007 before donors know what they will be able to do under the post-interoperability EHR rule, and it could take much longer than that if the expected date for interoperability standards turns out to be optimistic. This makes budgeting for donations very difficult and delays EHR adoption by physicians unnecessarily and unwisely.

Given the enormous benefits in saved lives, improved outcomes, and decreased medical costs of early and rapid adoption of EHR systems, CMS should not write a pre-interoperability rule that is narrower than the post-interoperability rule, except to the extent needed to prevent patient and program abuse related to the lack of interoperability standards.

A. Eliminate Unnecessarily Restrictive Definitions and Uses of EHR

We incorporate all of the comments on the post-interoperability rule into our concerns regarding the pre-interoperability rule, in those areas in which both the post-interoperability rule and the pre-interoperability rule are not permissive enough to meet the policy objectives behind widespread adoption of EHR. Additionally, we are concerned about aspects of the pre-interoperability rule that are narrower than the post-interoperability rule in the following areas.

1. Eliminate the "Used Solely" Language in § 411.357(w).

We believe the "necessary and used solely" language in the pre-interoperability rule should be abandoned, for the same reasons we discussed above with regard to the word "necessary" (*see* Section II.A.3.), CMS does not explain why it is proposing to carry over the "used solely" language from the e-prescribing rule to the pre-interoperability rule, and we are not aware of a good reason for doing so. CMS can adequately protect against program abuse related to donations being used to support functions unrelated to EHR by requiring that the donations are "used in connection with" EHR functions.

2. Revise the Restrictive "Takes into Account" Volume or Value Limitation in § 411.357(w)(4).

The failure to have more donor-friendly "volume or value" language, as described in our discussion of the post-interoperability rule (*see* Section II.C.), is the primary reason some of the sponsors of this letter do not intend to make any pre-interoperability donations unless the final pre-interoperability rule is broadened. As good stewards of limited funds for EHR donations, we need to be able to target donations to physicians with whom we share the most patients or on the other factors discussed above. We do not see any risk of program abuse pre-interoperability that would not also be present post-interoperability, and the rules thus should be identical.

3. Avoid the Exclusion of "Any" Administrative Software in §411.357(w)(8).

This language is not present in the post-interoperability standard. While we do not oppose exclusion of administrative software from the protection of these rules, as discussed above (*see* Section II.A.1.), the ability to include a patient portal, which includes some scheduling software, is important to some potential donors. The fact that EHR software has some coding functionality built-in also concerns us under this restrictive language. We urge CMS to adopt the same approach in the pre-interoperability standard as we have advocated above post-interoperability. This restriction is another reason why some of the sponsors of this letter will take a wait and see approach until the post-interoperability rule is adopted or an expanded pre-interoperability rule is finalized.

B. Maintain Conditions that Prevent Program Abuse in the Pre-Interoperability Rule

We fully support the open use requirement in § 411.357(w)(2) and believe it goes a long way toward addressing CMS's concerns about program abuse in the pre-interoperability era. Further, in the post-interoperability discussion, we emphasize the importance of protecting technical support, including technical support that would allow an entity to evaluate whether a physician's existing EHR system (which may have been donated by another entity) can effectively communicate with the donor's system or with a community health information network (*see* Section II.A.2.). We believe this should also be applied to the pre-interoperability rule, and would reduce the likelihood of stand-alone systems or of non-technological barriers to connections between systems.

To further address CMS's concern about program abuse pre-interoperability, we would support an additional condition that would require donated EHR software to be subject to contract terms that require that it will be updated or upgraded to meet interoperability standards within some reasonable time after they are adopted. While donors could not guarantee that the vendors who make such promises will actually be able to succeed in making the donation interoperable, we expect that most vendors will both accept such language (because many are doing it now) and will in fact comply (because otherwise they will go out of business due to inability to sell their product).

We believe the conditions suggested above are sufficient to protect against reasonable concerns with program abuse pre-interoperability. Otherwise, the CMS exceptions should be identical pre and post interoperability, with both written to reflect the considerations discussed above with regard to the post-interoperability rule.

IV. Conclusion

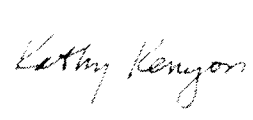
The sponsors of this comment have a wealth of experience with implementing EHR and struggle with the challenges of making EHRs more effective in improving the quality of patient care. Despite the challenges and occasional setbacks, we are excited by the potential of EHR systems to fundamentally transform patient care.

These proposed rules are exceptionally important to our ability as potential donors to encourage the adoption of EHR, wholly without regard to the impact on referrals. We do not expect any of our donations of EHR software or support to affect the volume of referrals we receive, except to the extent that those referrals are more likely to be subject to clinical protocols and alerts and to scheduling for needed tests and services. None of the changes in referrals will be directly related to the donation of EHR to induce referrals. Any change in referrals will be due to improvements in care made possible by EHR.

If it would be useful to CMS to discuss details of how EHR systems work "on the ground," to understand the contracting process or the need for constant technical support, or to gain insight into any aspect of EHR adoption, please contact us. We have years of hands-on experience and are eager to share it in order to improve CMS's proposed EHR exceptions to the Stark self-referral law. Thank you for your consideration of our comments.

Sincerely,





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

Re: File Code OIG-405-P. Comments on Proposed Electronic Health Records Safe Harbors

To Whom It May Concern:

We are writing on behalf of health care organizations committed to electronic health record (EHR) systems designed to improve quality and facilitate "a connected system of electronic healthcare information available to all doctors and patients whenever and wherever necessary."[39] The health care organizations sponsoring this comment are: Banner Health, Billings Clinic, The Cleveland Clinic Foundation, Intermountain Health Care, Partners HealthCare System, Inc., Scottsdale Healthcare Hospitals, and St. Joseph's Hospital.

This comment addresses the OIG's Notice of Proposed Rulemaking on Proposed Electronic Health Records Safe Harbors, 70 Fed. Reg. 59015, 59021-24 (October 11, 2005). We have submitted substantial comments on the parallel proposed Stark exceptions for electronic health records (EHR), which we have attached to this comment and incorporate fully into our comments to the OIG because the concerns are similar for anti-kickback statute (AKS) safe harbors.

The Stark physician self-referral exceptions and the anti-kickback safe harbors differ in two ways that are important to this comment. First, the AKS safe harbors apply to a much broader range of potential permissible recipients of EHR donations. Second, the AKS safe harbors are not mandatory and, therefore, allow for enforcement discretion not to pursue conduct outside of the safe harbor. Furthermore, the availability of individual

[39] Commission on Systemic Interoperability, "Ending the Document Game: Connecting and Transforming Your Healthcare Through Information Technology," at 2 (October 2005) (hereinafter 2005 Commission on Systemic Interoperability Report).

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case-by-case advisory opinions under the AKS gives potential donors a way of seeking comfort that a business strategy they believe benefits patients, but may be perceived by some as intended to induce referrals, is legally acceptable. The implications of these differences for the AKS safe harbors are discussed below.

Permissible Recipients

Consistent with the policy objective of connecting "all doctors and patients whenever and wherever necessary," we see no reason to limit potential recipients to those identified in the e-prescribing regulations. Indeed, interoperability and other forms of "connection" between physicians and other health care providers require that they all have an electronic record.

In particular, patients in post-acute facilities and settings, who often have complex medical conditions involving multiple prescriptions, should have their records available in an electronic format and subject to the clinical protocols and alerts built into EHR systems.[40] Health care organizations, including the sponsors of this comment, often provide physician medical direction to nursing homes. Those medical directors are frustrated about the lack of EHR in nursing homes. The slow rate of adoption of EHR in nursing homes[41] (less than 5%, according to MedPAC) increases the likelihood of errors for some of the most disabled patients, with long term chronic conditions, who are often cared for by a large number of different physicians and other providers. Diabetes is also common among residents of nursing homes. The failure to implement EHR in these settings means that it is much more difficult to know if diabetic care is being managed according to clinical protocols built into the EHR. The health care organizations that provide physician medical directors should be allowed to target donations to nursing facilities that care for the same patients.

Furthermore, laboratories, ambulatory surgery centers, radiation oncology centers, federally qualified health centers, physicians' assistants, nurse practitioners and the full range of other Medicare providers need to be connected into an interoperable electronic health record. The movement toward interoperability between providers will occasionally require a larger system, with sophisticated IT staff, to help evaluate and correct problems within another provider's EHR that is inhibiting communication between EHR systems. In the Stark comment, we have emphasized the importance of donations of technical support to physicians. For the same reasons, donations of technical staff time to help improve the EHR of any health care entity that takes care of patients should be allowed. Doing so is likely to actually reduce the likelihood of "stand alone" systems.

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[40] MedPAC, March 2005 Report to Congress, Chapter 4.
[41] Ibid. at 207, 208.

The AKS Safe Harbors Could Be More Restrictive in Some Areas than the Stark Exceptions

We believe that the Stark exceptions and AKS safe harbors should be parallel, except in those areas where an honest, unintentional mistake in a documentation, valuation, or certification requirement should not create automatic penalties under the Stark laws. If CMS and the OIG decide that these are necessary conditions, we encourage the OIG to give them effect through the AKS safe harbors and CMS to give them effect by incorporating compliance with the AKS into the Stark exceptions.

For reasons discussed in the Stark comment, we believe that the following conditions, if included in the final rules, should be requirements only under the AKS safe harbors:

- A cap on the value of donations,
- Documentation of donated items and services,
- Documentation of the "value" of those items and services for each physician or other entity that receives a donation
- Certification by donors and recipients that the donations are not "technically or functionally equivalent" to technology already possessed by the recipient.

Under the AKS, failure to meet these requirements would be penalized only if that failure is an intentional effort to induce referrals, not when failure to comply is a harmless, unintentional mistake with substantial potential penalties.

If CMS and OIG impose the same cap, valuation, certification, and other documentation standards under both laws, the effect will be to create more substantial penalties for violations related to donations to physicians, relative to other providers, and, therefore, more substantial legal risks in making donations to physicians. Harmless, unintentional mistakes will be punished when applied to physicians under the Stark law, but not to donations that are only subject to the AKS. The in-house counsel of the sponsors of this comment have assured us that the consequence is likely to be heightened concerns about donations to physicians because the donor must create a fail-safe and expensive compliance structure for valuation, certification, and documentation that does not allow even for honest mistakes.

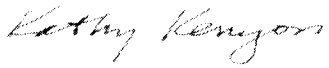
Conclusion

If it would be useful to the OIG to discuss details of how EHR systems work, to understand the contracting process or the need for constant technical support, or to gain insight into any aspect of EHR adoption, please contact us. The sponsors of this comment have a wealth of experience and are eager to share it in order to improve the OIG's proposed EHR safe harbors.

Sincerely,

Joel Wakefield

Kristen Rosati



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A. Covered Technology

It is vitally important that any new rule provide for a broad definition of electronic health records and a wide array of uses of electronic health record systems. The proposed EHR rule language is too narrow to encourage the known benefits of EHR adoption in physician offices as characterized by the Commission on Systemic Interoperability, Institute of Medicine, and the Medicare Payment Advisory Commission (MedPAC).[9] The proposed rule limits protection to "[n]on-monetary remuneration (consisting of items and services in the form of software or directly related training services) necessary to receive, transmit, and maintain electronic health records" under specified conditions.

1. Adopt a Broad Definition of the Protected EHR System

Determining what is included in the protected EHR is fundamental to the ability of potential donors to safely donate, especially because of CMS's concerns about improper subsidies of administrative systems that are extraneous to the EHR. In our view, the protected EHR should be defined broadly to cover far more than the mere medical record in electronic format.

CMS has asked for comments on the definition of "electronic health records." 70 Fed. Reg. at 59188. We believe the definition should be designed to accomplish at least two well-established objectives of EHR systems.[10] First, it should promote "a connected system of electronic healthcare information available to all doctors and patients whenever and wherever necessary."[11] Full information exchange among providers reduces errors and improves quality. Second, EHR systems should be a tool for collection of quality and outcomes measures to facilitate pay-for-performance payment methodologies. CMS is a major proponent of such measures, so we will not describe them further in this comment.

In discussing "covered technology," CMS has expressed its intent to protect "integrated packages that could positively impact patient care," while avoiding protection of administrative software that does not also further the goal of improving patient care.

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[9] 2005 Commission on Systemic Interoperability, supra; Institute of Medicine, *Crossing the Quality Chasm* (2001) and *Quality Through Collaboration: The Future of Rural Health* (November 2004); MedPAC, March 2005 Report to Congress, Chapter 4, "Strategies to improve care: Pay for performance and information technology. See also research on how EHR is actually used in small physician offices. R. Miller, et al, "The Value of Electronic Health Records in Solo or Small Group Practices," 24 Health Affairs 1127 (September/October 2005).

[10] We would also like for CMS to consider a third objective – protecting the privacy and security of EHR systems. If this were added as a goal, then EHR systems, as defined in these rules, would also include auditing and security functionality to prevent and detect privacy breaches. Auditing software is often a separate add-on component of an EHR system. Although EHR software is typically designed to capture the information needed for an audit, getting that information out of the EHR system often requires purchase of separate auditing software or special programming.

[11] 2005 Commission on Systemic Interoperability Report, at 11 Executive Summary. See also MedPAC, March 2005 Report to Congress.

70 Fed. Reg. 59188 and 59190. Consistent with CMS's intention, MedPAC in its March 2005 Report to Congress explicitly embraced EHR as a valuable tool in achieving the two objectives above – promoting connectivity to achieve quality and measuring outcomes – and made a distinction between EHR clinical information technology systems and other "administrative systems." MedPAC describes an EHR "clinical information technology" (IT) system as follows:

> Clinical IT comprises multiple applications that support different functions in health care, such as:
> - tracking patients' care over time (the electronic health record);
> - allowing physicians to order medications, lab work, and other tests electronically, and then access test results (computerized provider order entry);
> - providing alerts and reminders for physicians (clinical decision support systems); and
> - producing and transmitting prescriptions electronically (e-prescribing).[12]

All of these functions, not just the first narrow view of EHR as a method of "tracking patients' care over time," should be protected by CMS in the EHR exception (whether CMS regards the functions as mandatory or optional).

MedPAC also discusses specific "functions" and "outcomes" of clinical information technology, especially important for allowing measures of quality and outcomes. The "functions" include: registry for patients with chronic conditions; registry for all patients; system for tracking patients after an acute event to determine follow-up; system for tracking test results and prompting follow-up of abnormal tests; medication safety checks (allergies, dose, age, drug-to-drug interactions); system for decision support within the patient encounter; system for tracking lab results, including status of patient notification; and system for aggregating, measuring, and monitoring patients by category, such as disease, medications or age.[13] The "outcomes" of clinical information technology identified by MedPAC include: patients with chronic conditions tracked and sent reminders prompting office visits or other necessary follow-up; patients in the practice screened for risk factors; patients who are identified as at-risk are contacted; patients with potential drug-to-drug interactions are contacted; patients are contacted to communicate lab results; and quality measured internally and care management improved.[14]

We recommend that the definition of EHR used in the CMS exception be at least as encompassing as the MedPAC definition of clinical information technology, and that CMS articulate a presumption that software falls into the protected definition of EHR if it

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[12] MedPAC 2005 Report to Congress at 206.
[13] MedPAC 2005 Report to Congress at 198.
[14] MedPAC 2005 Report to Congress at 198.

is designed, marketed, or reasonably used in a way that substantially fits any element of that definition. Further, CMS should state that software designed primarily to further the functions and outcomes of EHR described by MedPAC (or other similar functions and outcomes as the technology develops) is deemed to meet the definition of protected EHR.

If the "outcomes" MedPAC identified above are deemed to fall into the definition of EHR, a "patient portal" that includes communicating with patients about the full range of clinical issues, such as scheduling, appointment reminders, and alerts, will be protected. In addition, as the Commission on Systemic Interoperability has pointed out, the ability of patients to electronically access their own EHR information, such as results of lab tests, will become increasingly important to improving patient care. Patient portal software is designed to facilitate a broad range of patient communications. Therefore, we recommend that CMS include patient portal software, including a scheduling function, in the definition of protected EHR.[15]

We also believe that the CMS exception should extend to donations of any element, component, or function of an EHR system, because building an EHR system incrementally over time makes sense. That is, in fact, how most of the organizations sponsoring this comment have built their own EHR systems. Donors should be able to donate an element of an EHR system or special programming to support a particular patient care goal, such as a specific clinical protocol that can be added to an existing EHR system.

CMS should not require that a donation have all of the elements CMS regards as "core" to an EHR. For instance, the organizations sponsoring this comment strongly believe in computerized provider order entry (CPOE), and believe it must be included in any definition of a protected EHR system; however, we do not believe that donations should be *required* to include CPOE to be protected. Similarly, while we strongly believe that providing access to an electronic medical library should fall into the definition of a protected EHR system because it is part of clinical decision support,[16] we would certainly not argue that it must be included in order for the donation to be protected, although we believe donors should be allowed to donate it as an addition to an existing EHR system. Trying to force broader EHR system adoption by only protecting EHR donations that include defined "core" elements is likely to have the unintended consequence of discouraging donations of important components of a system.

While the sponsors of this comment support an expansive definition of EHR, we do not believe that the protected software must include certain types of clearly separable administrative software (e.g. billing, coding, or practice management software), except software, such as the patient portal, that is related to communications with patients,

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[15] The importance of a broad definition of EHR that includes patient communications is also emphasized in the 2005 Report by the Commission on Systemic Interoperability.

[16] For a discussion of the important of electronic medical libraries, especially to generalist physicians in rural areas, see The Institute of Medicine, Quality Through Collaboration: The Future of Rural Health, at 155 (2004).

including scheduling and reminders. However, we urge CMS to make it clear that elements of an EHR system that incidentally facilitate administrative functions will not remove it from the protection of the rule. For instance, EHR systems have links to diagnosis codes used by physicians to describe patient care and to engage in order entry, as well as supporting coding and billing administrative software. EHR systems are increasingly able to identify whether a service is considered "medically necessary" by Medicare, which is useful both clinically and administratively, allowing the EHR to generate advanced beneficiary notices (ABNs) that support billing. The elements of an EHR that support administrative functions, as well as patient care functions, are highly valued by physicians; indeed, these dual use functions are often a major reason physicians begin to use an EHR. Not only is it practically impossible for donors to remove such functionality from EHR system donations because of how the software is designed, but it would reduce the use of these systems by physicians, and, therefore, the benefits to patients. So while we believe CMS must allow certain administrative features to be included within the definition of protected EHR software, we agree that administrative software that is not integrated into the clinical EHR does not need to be protected.

2. Include Technical Support

One major reason for slow EHR adoption by physicians is lack of available technical support to acquire and maintain an EHR system.[17] Painful and expensive experience with installation of software over the past decade has demonstrated that reliable technical support is essential to successful implementation and ongoing maintenance of any software system. All of the sponsors of this letter have built substantial internal IT support services. None of the sponsors of this comment would have considered implementing an EHR system without having in place both reliable internal technical support (often called the "help desk') to address routine questions and diagnose problems, as well as outside technical support to solve problems internal IT staff cannot solve and to provide ongoing updates and upgrades to the system.

As a practical matter, EHR software must interface with administrative software, and technical support will be required to make those interfaces work. Organizations that adopt EHR systems will have previously begun the journey toward electronic systems with some kind of administrative software (given Medicare requirements, they probably started with electronic billing software), and that software will need to interface with the EHR software.[18] To avoid repeated collection of demographic and payor information from patients, interfaces with the billing and practice management software must be

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[17] MedPAC March 2005 Report to Congress at 207, 212. "Few providers, and especially those in smaller settings, know enough to navigate a large and complex market of IT products, implement their choice, and maintain a system over time. . . . These difficulties have led to implementation failures."

[18] See R. Miller et al, supra, at 1129, indicating that EHR systems in small physician practices interface with billing.

developed. Coding software, designed to support coding and reduce mistakes, also should interface with EHR software.[19]

Donations of technical support should be protected, even if not accompanied by donations of EHR software, as long as the technical support is connected to the acquisition or use of an EHR system. This will reduce the likelihood of program abuse by allowing donations of EHR technical support to physicians who want to evaluate how an existing EHR system can better communicate with other EHR systems. For instance, if a physician received some of his EHR system from one vendor or donor and wants to know how it can be made to communicate with another system, the other system should be able to donate technical support to make that assessment. Doing so will promote interoperability and connectedness, and reduce the ability of any single donor of EHR to work exclusively with a physician. Donations of technical support will also promote connecting different EHR systems into community health information networks, as they develop. Furthermore, the Department has made the EHR software used by the Veteran's Administration, VistA, available to all physicians, for free. Physicians in small practices may find this attractive, but only if they receive technical support to evaluate the appropriateness of the software for their practices, to install it, and to maintain it over time. Donors should be allowed to donate technical support of EHR software, including interfaces to administrative software and connections to other EHR systems, even when they do not donate that software themselves.[20] Without such protection, many EHR systems will not be properly installed or maintained in physicians' offices, both negating the benefits of the system and souring many physicians' perceptions of the benefits of EHR.

We therefore urge CMS to write an exception that allows donations of technical support at all stages of EHR acquisition, implementation, and maintenance, including support of the interfaces to related administrative software and connections between EHR systems. Furthermore, as discussed below, because of the difficulty of valuing technical support and because such donations will not lead to program abuse under the conditions recommended in this comment, we recommend that it be removed from any cap CMS might consider and from any obligation to "value" donated EHR-related services.

3. Remove the Requirement that Donations Be "Necessary"

Even if CMS adopts a more expansive definition of EHR, it should remove the limitation implicit in requiring that the donation be "necessary" to receive, transmit, or

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[19] The DHHS Office of National Coordinator for Health Information Technology, working with AHIMA, has initiated programs that would use information technology to reduce Medicare fraud. See http://www.hhs.gov/healthit/hithca.html. In addition, we urge CMS to recognize that some coding functionality must be built into and protected as part of the EHR software in order to facilitate an effective interface to separate coding administrative software.

[20] One obvious place where technical support will be crucial is in making the upgrades to interoperability. Any organization should be able to donate IT staff to help make its system interoperable with other providers' systems.

maintain EHR. While CMS does not discuss "necessary" within the context of the EHR exception, it states that it has the same meaning as "necessary" in the e-prescribing regulation. 70 Fed. Reg. at 59184-85. There, the term is mainly discussed with regard to e-prescribing hardware, specifically a hand-held device capable of transmitting electronic e-prescribing information, and the word "necessary" is used to prevent duplicative donations of "technically or functionally equivalent" hardware.

In the context of the EHR exception, which, if the recommendations in this comment were adopted, would apply only to EHR software, training, and technical support, there is no hardware equivalent to which the term "necessary" would apply. We do not know of a reasonable way to evaluate whether software, training and technical support is "necessary" or "technically or functionally equivalent" to anything the recipient possesses.[21] Would this require a donor to determine, for each and every potential recipient, if a higher quality EHR related donation is really "necessary" if a lower quality one might do? When a requirement is difficult to determine and carries substantial penalties for mistakes, lawyers will recommend hiring expensive outside experts,[22] diverting scarce resources from beneficial EHR donations and into documentation and certification efforts. Indeed, the potential for confusion, uncertainty, and perceived legal risk may be higher in this section than any other in the proposed rule. Moreover, we fail to see how either the word "necessary" or the related certification requirement prevents program abuse, as long as the donation is connected to legitimate EHR functions.

Dropping the word "necessary" from the language of this section would break the connection to the e-prescribing rule's use of the term and to the certification requirement that donated technology not be "technically or functionally equivalent" to what the physician possesses at the time of the donation. We recommend replacing "necessary" with the less restrictive phrase "used in connection with."[23] It would also eliminate the need to determine if donated EHR software is "necessary" if free software, such as the VistA software, is "technically and functionally equivalent." The "used in connection with" language sufficiently limits the donation to EHR functionality, without allowing donations that support other aspects of a physician's professional or personal activities.

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[21] Vendor EHR software is packaged with components that owners can turn off or on when they need that component. Therefore, it's possible that donated software will have a component that no one intends to use, but is built into the system and may be "technically or functionally equivalent" to something the recipient already has.

[22] If the certification standard remains, CMS should allow monetary donations to pay for certification experts.

[23] This phrase comes from the CMS discussion of the purpose for the word "necessary" in the e-prescribing reg. 70 Fed. Reg. at 59184.

4. Clarify That the Limitation to "Nonmonetary" Donations Allows Payment for Licenses and Users' Fees

In many cases donors will make EHR systems available to outside physicians by paying a user's fee or licensing fee to the vendor of the donor's EHR system, in accordance with the contract between the donor and the EHR vendor. CMS needs to make it clear that this payment, because it is necessary to the donation of the EHR, is protected by the CMS EHR exception. CMS also needs to make it clear that the outside physician and the donor system can split this fee (on some basis unrelated to the volume or value of referrals), which would effectively allow the donor to subsidize the physician's acquisition of the EHR system, without covering the full costs. Furthermore, consistent with the discussion below of permissible recipients, the donor system should be allowed to give all of the physicians in a targeted physician's group, employer, or network (who tend to share coverage and call) the ability to be added as users by payment of the user's fee or license fee, whether or not the donor chooses to subsidize some part of the fee.[24]

B. Permissible Donors

In this section, we urge CMS to permit any entity subject to the Stark law to donate to physicians—even those that are not on the "medical staff" of hospitals or members of group practices—as long as three conditions are met: (1) the donor and physicians share care of patients, (2) the donor has a legitimate reason for making the donation that is not "directly related to" the volume or value of referral services, and (3) the donation otherwise complies with reasonable conditions.

CMS should explicitly allow a donor "entity" subject to Stark to use a separate, but related organization, such as a Management Services Organization (MSO) or an independent practice association (IPA), as a vehicle for donations protected by this rule.[25] In addition, there is no reason to exclude post-acute facilities (nursing homes and home health agencies), laboratories or ambulatory surgery centers, each of which may have a special component of an EHR that may be especially useful in improving patient care in their area of expertise, as long as the donation is related to care of shared patients. Indeed, allowing more potential donors may actually **reduce** the risk of program abuse.

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[24] Please see the discussion in the "preliminary comments" in Section I, requesting that CMS state that a large system may make its EHR system available to outside physicians for use in their offices by passing through a users fee or licensing fee, and that doing so is considered "fair market value."

[25] The MSO or IPA itself may not be an "entity," as defined by Stark, but, through it, the sponsoring organization, which is an "entity," will have an indirect compensation arrangement with physicians. Donations through the MSO by the entity should be protected by this rule.

C. Permissible Recipients and the Selection of Recipients

As currently written, the rules allow hospitals to donate only to members of the medical staff who "routinely furnish services at the hospital,"[26] group practices to give to their own employees and members, and prescription drug plan (PDP) sponsors and Medicare Advantage (MA) organizations to give to physicians. On this point the rule is unnecessarily narrow and fundamentally contrary to the goal of connecting all physicians and other providers to health care information whenever and wherever needed.

Given the policy objective of encouraging rapid adoption of EHR systems that connect all physicians and patients in all practice settings to all relevant clinical information, the exception should allow any entity subject to the Stark law to donate to physicians—even those who are not on the "medical staff" of the donor's hospitals or members of group practices—as long as the three conditions previously mentioned are met, *i.e.* donor and physicians share care of patients, the donor has a legitimate reason for making the donation that is not "directly related to" the volume or value of referral services, and the donation otherwise complies with reasonable conditions.

As potential hospital donors, we believe limiting permissible recipients to members of the medical staff is far too narrow and will leave many of the patients we serve without a way of including all of their health information into an interoperable EHR. All of the sponsors of this comment have a large number of employed physicians or physicians on the medical staff who regularly provide consulting and care to patients who use physicians who are not on the medical staff.[27] EHR is another tool for taking care of patients, and it should naturally develop among physicians who share patients. As a practical matter, physicians are more likely to adopt EHR if they can work with the larger systems they already rely upon for specialized care of patients. We also believe that group practices should be able to donate to physicians who are not members, employees or independent contractors, under the same criteria that should apply to hospitals.

By widening the range of permissible recipients to include physicians who are not on the medical staff of the donor hospital, CMS will more effectively promote true interoperability and improve the quality of care that comes from physicians and patients being connected to health information whenever and wherever needed than by any other change in the proposed rules. This is because these physicians, by definition, have their primary hospital affiliation with another hospital, and consequently will want the donor's

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[26] The quoted language comes from CMS's discussion of the e-prescribing rule, which, we assume, would also apply to the EHR exceptions.

[27] Several sponsors of this comment routinely provide subspecialty care and consulting to patients in rural areas. The primary care physicians of those patients are not likely to be on the medical staff of a hospital that has EHR or is in a position to donate. When one considers that EHR adoption in rural areas lags behind the slow adoption by physicians in urban areas, this failure of the proposed rule to allow donations by large organizations to rural physicians with whom they regularly share patients is especially troubling. See generally IOM, *Quality Through Collaboration: The Future of Rural Health* (November 2004).

EHR system to be interoperable with the system that is developed at their primary hospital.

Given the purposes behind EHR adoption, the comment sponsors hope to use the CMS EHR exception to target donations, incrementally and over time, as technology develops and budgets allow, to maximize the benefit of the donations around legitimate objectives. Donations would consider a number of objectives, including connecting physicians with whom we share the most patients (thus maximizing the benefits of EHR to the largest number of patients); connecting physicians who treat specific diseases or have medical concerns[28] we have targeted for improvement through use of EHR; connecting physicians who work together to achieve quality outcomes or pay for performance objectives that would be advanced by use of a common EHR; and connecting our physicians and facilities with "safety net" providers who often serve the uninsured and do not have the resources to adopt an EHR without help. We believe we can achieve these objectives under the language in the proposed post-interoperability exception that allows donations if "neither 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," but only if "directly related to" is interpreted to allow donations to achieve the legitimate objectives identified above.

We support CMS "deeming" certain conduct to be permissible under the "directly related to" standard, and are especially supportive of the "deemed" standard allowing donations if the "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." § 411.357(x)(4)(vi). However, we are concerned that the conduct "deemed" acceptable be broad enough to allow the proper identification of potential recipients, such as on the basis of the factors suggested above.

It is absolutely vital to a donor's ability to donate to be able to distinguish between allowable donations (even those indirectly related to or correlated with referrals), from impermissible donations (those "directly related to" referrals). For instance, organizations with a reputation for treating heart disease or that have agreed to measure outcomes related to heart disease may want to target EHR donations to primary care physicians who routinely consult with the cardiologists employed by the donor, even if the primary care physicians do not have medical staff privileges at the same hospital as the cardiologists. After all, cardiologists need to know about the primary care received by their heart patients and need to have those primary care physicians follow clinical protocols, which are built into EHR systems. The fact that the treatment of heart disease, by its nature, involves substantial referrals of designated health services should not make

[28] An example of a medical concern would be controlling post-operative infections by improving both pre-operative and post-operative patient care, which means that outside physicians must be connected with the surgeons.

that donation suspect. To the contrary, it should be welcomed as a way to improve care and reduce hospitalization of heart patients.

Therefore, we strongly urge CMS to recognize that permissible potential recipients of donations include any physician (not only those on the medical staff), as long as the donor consistently applies criteria for establishing eligibility for a donation based upon legitimate business and clinical considerations not directly related to the volume or value or referral services or to a strategy of shifting referrals. CMS should then deem that the following considerations are allowed in choosing recipients:

1. Physicians within a defined geographic area who have historically shared a minimum number of patients with the donor, the donor's employed physicians or clinicians, or physicians on the donor's medical staff;

2. Physicians within a defined geographic area who have historically shared a minimum number of patients who have a particular disease or medical concern with the donor, if the donor is donating software or services that will improve the care of the physicians' patients with that disease or concern;

3. Physicians in a health plan network of which the donor is also a participant or who are otherwise involved in a program to measure outcomes with the donor (such as a CMS pay for performance demonstration program), if the physician has agreed to outcomes or pay for performance measures that would be advanced by use of an EHR system; and

4. Physicians within a defined geographic area who can demonstrate that they serve a large underserved patient population and can meet financial need criteria established by the donor, whether or not the donor and physicians share a specified number of patients.

In applying the above criteria for identifying permissible recipients, the following must be allowed if donors are going to be able to reasonably control their operations and respond to unexpected circumstances:

1. If identifying a minimum number of shared patients is required, as suggested above, the donor (rather than CMS by rule) should be able to specify that number; otherwise the donor cannot reasonably adjust that number to remain within its budget.

2. The donation should be allowed to be given not only to individual physicians, but also to the physicians' group or employer (because if a physician is in a group or employed by a health care entity, he or she will acquire EHR through the group or employer) or any network or IPA the physician may be using to acquire EHR. If the donation is given to the physician's group or employer, everyone in the group

involved in care of shared patients should be allowed to use the donated technology and services.[29]

3. The donor should be allowed to decide not to give a donation if it determines a physician, physician group, physician employer, or physician network should be excluded on some legitimate criteria,[30] even if it means that individual physicians who otherwise meet the criteria for receiving a donation are excluded.

4. The donor should be allowed to suspend donations or change criteria for making donations at any time to address unforeseen business and clinical concerns, developing technology, technical support problems, the need to comply with government regulations, and other legitimate considerations not directly related to selection of recipients based on the volume or value of referral services.

D. Value of Protected Donations

We urge CMS not to cap EHR donations. As potential donors, it is quite clear that the other requirements of this proposed rule and sheer economic reality will prevent excessively large donations that raise a realistic likelihood of program abuse, especially given the Stark incorporation of the anti-kickback statute, which would punish unusually large donations intended to induce referrals. The sponsoring organizations do not expect to make large donations to individual physicians or their practices.[31] Thus, while a cap may actually be in the economic best interests of potential donors, we oppose such a measure because it is expensive and difficult to track, especially under a strict liability law where harmless mistakes (such as the failure to correctly identify the donation or to correctly calculate or document its value) create substantial penalties.

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[29] We urge CMS to specifically address how donors can make donations to a physician's employer, group practice, or network. For instance, if a physician in a group is eligible to become a "user" under eligibility criteria established by the donor, then all of the physicians who share care of patients within the group also need to be "users" as a practical matter. If the way a donor makes someone a "user" is by adding him to the license it has negotiated with a vendor, then the donor should be allowed to add all of the physicians in the group as users, upon payment by the group of the direct, incremental costs of the donor. If these direct, incremental costs are considered a fair market value payment, then existing law would allow it. This is, therefore, one of those areas in which clarification of "fair market value" by CMS would be enormously helpful.

[30] The legitimate reasons for not making a donation to an otherwise eligible physician might include: the physician has no real interest or need, which might lead the donor to expect the physician would not use the donation (e.g. imminent retirement) or the potential recipient already has or is planning to acquire elements of an EHR system, even if not functionally equivalent to the software or services being donated.

[31] For instance, given existing internal methods of identifying costs and budgeting, none anticipates donating more than a total of $35,000 per physician, and most expect to spend far less than that, more in the range of up to $5,000. This number, however, would be dramatically impacted by the items or services the donor is required to value under the cap. One of the reasons we oppose the cap is the difficulty of foreseeing the future value of everything that is necessary to make EHR effective that might be included under the cap.

If CMS and OIG believe a cap is necessary to prevent program abuse, we encourage that application of the cap be limited to the anti-kickback safe harbors. An alternative to the cap might be to suggest that relatively large donations targeted on high volume referral sources may be subject to special scrutiny to determine if the donations otherwise meet the requirements of the Stark EHR exception.

If CMS believes a cap is necessary under the Stark exception, we urge CMS to remove from the cap EHR related donations that are not likely to be abused or are difficult to value prospectively. Based on substantial experience, we know that physicians do not enjoy spending extra time on either training or technical support. They want to know how the EHR system works (therefore they want training for themselves and their staff) and they want the system to work as it is suppose to work (therefore they want reliable, timely technical support). They do not want trainers or technical support staff hanging around unnecessarily. These functions are, therefore, by their nature not subject to abuse. CMS can effectively deal with inappropriate use of the donor's training and support staff by imposing a condition that donations be connected to EHR functions, and not to other office or personal matters. Indeed, we believe the "used in connection with" language suggested above (as a replacement for "necessary') would create a link between donated services and EHR related functions.

Donations of updates and upgrades should be excluded from any cap because they are difficult to prospectively value and occur often to bring the EHR into compliance with new laws and regulations or to introduce or improve evidence-based clinical protocols and alerts. We expect that interoperability will require constant updates and upgrades over time in EHR systems.[32] CMS should encourage constant improvement in EHR systems. Imposing a burdensome requirement of valuing and documenting such donations will reduce innovation and improvement. Furthermore, it is difficult to see program abuse resulting from this kind of donation.

CMS should not cap donations to "safety net" providers, as described above, including physicians in nonprofit and governmental entities that meet some standards of community service and financial need.

Finally, to the extent CMS believes a cap is necessary, it should give donors the maximum flexibility to address any cap requirement. Donors should be able to limit donations to a certain amount per physician or to a percentage of the value of the donation subject to the cap, in their discretion. The cap should be a life-time cap, rather

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[32] Other examples are numerous. If CMS includes privacy and security features into its definition of protected EHR software, which we advocate, then improvements in auditing and encryption software should occur. CMS constantly changes diagnosis codes and standards of medical necessity that are built into EHR systems. CMS is likely to encourage use of coding and billing software to improve operational efficiency and reduce mistakes, and since CMS constantly changes the coding and billing rules, updates and upgrades are necessary, including testing and improving the interfaces of those systems with the EHR system. CMS should not burden these kinds of improvements by subjecting them to a cap, and valuation and documentation standards.

than constrained into a short number of years, and it should be an aggregate cap, rather than an annual cap. CMS should accept any reasonable, objective methodology to value services under the cap, including approximations.

E. Certification and Documentation Requirements

For reasons discussed above (*see* Section II.A.3.), we oppose the certification requirement in §411.357(x)(5) and (6) that would prevent donation of items or services that are "technically or functionally equivalent" to those already possessed by the physician. As explained in more detail in the prior section, this requirement is neither necessary to prevent program abuse nor realistic as a practical matter when applied to donations of EHR software, training, and technical support. If required at all, it should be in the context of the anti-kickback safe harbor where a technical failure to satisfy this requirement does not automatically trigger penalties.

With regard to the documentation standards in § 411.357(x)(5)(i)(ii) and (iii), while we recognize that it is consistent with other Stark exceptions to require a writing signed by the parties, specifying covered items or services and the value of those items or services, and covering all such services, we do not believe the same stringent documentation standards should apply in the very complex context of EHR. In particular, we urge that CMS drop the requirement documenting the "value" of the donated items and services, especially the training and technical support, for the reasons suggested above in the discussion in Section II.A.3. of the cap and the value of the donated items and services.[33] If documentation of "value" is required at all, it should be in the context of the anti-kickback safe harbor where a technical failure to satisfy this requirement does not automatically trigger penalties.

We also request that CMS not require that the writing specify in detail donated software, training, and technical support because of the difficulty—amounting to near impossibility—of doing so when much of what will be needed will occur after the initial donation and documentation. If required at all, such a requirement should be in the context of the anti-kickback safe harbor, where a technical failure to satisfy the requirement does not automatically trigger penalties. However, if CMS requires documentation specifying the items or services being donated, it should require only a general statement that the donor will provide training and technical support connected to EHR, in accordance with internal guidelines, and should not require valuation of training

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[33] As discussed earlier in this comment (*See* Section I), we would encourage CMS to explain what it means by "value," which we assume means the same as "fair market value," in this context, in order to promote the ability of organizations to use the existing exception in Sec. 1877(e)(8) for the purchase of items and services by a physician from an entity. We note that that requirement in the statute does not require a written agreement, as long as the payments are at "fair market value." The absence of burdensome documentation requirements make this attractive, but only if CMS draws a line between what is and is not remuneration in the context of EHR and describes reasonable methodologies for determining fair market value, including a pass-through of the organization's direct, incremental costs.

and technical support.[34] With regard to software donations, it should define updates and upgrades as covered by the initial donation, without requiring additional documentation, even if subsequent upgrades are discretionary and require payment of an additional fee.[35] Only donations of new software (not updates and upgrades of existing software) should need to be documented, and it should be acceptable for that to be done by an addendum or in any other reasonable manner, including e-mail communication between the donor and recipient.

III. Pre-Interoperability EHR Exception, § 411.357(w)

Our primary concern with the pre-interoperability rule is that its narrow scope will deter organizations, including the sponsors of this comment, from promoting EHR adoption until after the post-interoperability rules have been finalized. The pre-interoperability rule should not differ in substance from the post-interoperability rule, except in a few ways targeted at promoting interoperability, connectivity, and interface development between different EHR systems during the pre-interoperability period.

A narrower pre-interoperability exception cannot be justified based upon a reasonable concern with program or patient abuse, especially given reasonable conditions that promote ongoing efforts toward interoperability. For two reasons, we believe CMS's concerns about pre-interoperability program abuse related to the creation of "stand-alone electronic health records systems"[36] is based upon an inaccurate understanding of current developments in EHR systems and markets, as explained below.

First, interoperability is a process. Even now, as EHR software systems are being built piece by piece and updated constantly, organizations are continually working to create interfaces and connections that allow electronic communications about patients. The interfaces and connections are both within the EHR system—allowing, for instance, a hospital EHR system to access the lab system and the clinic records—and between the EHR system and administrative systems, such as billing and coding. Organizations also are actively working with vendors and other health care organizations on creating health information networks and on direct connections between different systems' EHR. Once

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[34] If it does require valuation of training and support services, it should specify that valuing the approximate direct costs of staff time suffices and that unexpected needs for training and support, even if not documented, will not violate this documentation requirement.

[35] It is, for instance, very likely that many EHR vendors will treat bringing their systems into compliance with interoperability standards as an upgrade, with a fee. The owner/licensee of the EHR system should be able to pay that fee without having to apportion the value of that upgrade to all outside recipients of donated software and without having to change the documentation related to donations.

[36] CMS writes at the beginning of the post-interoperability discussion: "We realize that variable (that is non-standardized) adoption of electronic health records systems could discourage market forces and competition from improving healthcare. Interoperability could mitigate many of our concerns regarding the potential anti-competitive effects of stand-alone electronic health records. We recognize that stand-alone electronic health records systems, even if widely adopted, may not deliver the error reductions, cost savings or marketplace changes necessary to meet the Secretary's goals, and could even shift the market toward more fragmentation." 70 Fed. Reg. at 59189-90.

physicians are accustomed to EHR and the benefits for their patients, they push to obtain electronic access to records as they or their patients move between facilities and different EHR systems. While CMS envisions the regulatory step from pre-to-post interoperability as a huge step, for EHR system vendors and owners that step will be simply the next step of an extended process they have been engaged in for quite some time.

Second, CMS suggests that some donors might see a market advantage to "stand-alone" EHR systems that would be anti-competitive.[37] We see none of this; indeed, we see that "stand-alone" systems are not favored in the market and will not last long in light of ongoing efforts to develop interoperability standards. Indeed, the path to interoperability and away from "stand alone" systems already exists in contracts. For years, purchasers of EHR systems have insisted upon and received contractual assurances that their systems will be updated or upgraded to meet federal standards as they are promulgated.[38] EHR systems (or, more likely, components of systems) that do not update or upgrade to meet interoperability standards will quickly become obsolete and will be replaced by others that meet those standards. Stand-alone systems will simply not continue to be supported post-interoperability based on any kind of perceived market advantage related to forcing referrals within the system. Physicians will not tolerate that kind of closed system once alternatives are available, because it is detrimental to patient care and is inconvenient. All of the sponsors of this comment, whether they have their own proprietary system or a vendor system, expect to meet interoperability standards in order to continue to have a system that is connected, rather than isolated.

Unfortunately, a narrow pre-interoperability proposed rule will seriously delay EHR adoption by causing donors, like the sponsors of this comment, to take a "wait-and-see" attitude until the post-interoperability rules are in effect. The sponsors of this comment are poised right now to begin EHR donations consistent with the comments in the post-interoperability discussion above. In some cases, donations were budgeted to begin in the first or second quarter of 2006. However, the sponsors of this comment would have serious difficulty making donations under the pre-interoperability rule, as proposed.

While CMS has stated that it expects interoperability standards to be adopted by the Secretary by the third quarter of 2006, we are concerned that this time frame may be optimistic. Furthermore, CMS has stated that it will not finalize post-interoperability rules until after the Secretary has adopted interoperability standards. 70 Fed. Reg. at

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[37] See quote in previous footnote. We question whether the concern with the anticompetitive nature of stand-alone systems falls within CMS's authority to address program and patient abuse. We also encourage CMS to contact either the Federal Trade Commission or DOJ's Antitrust Division with regard to its competitive analysis and concerns.

[38] Often the contract language in question requires that the software meet federal law and regulation, and makes that an ongoing obligation of the vendor, as long as the vendor provides support. That language has been effective in requiring vendors to create systems that can meet HIPAA privacy and security standards, as well as being able to send standardized bills electronically. Meeting interoperability standards will simply be another set of regulations requiring new programming or interfaces.

59190. That means that even if interoperability standards are promulgated by the third quarter of 2006, it is likely to be 2007 before donors know what they will be able to do under the post-interoperability EHR rule, and it could take much longer than that if the expected date for interoperability standards turns out to be optimistic. This makes budgeting for donations very difficult and delays EHR adoption by physicians unnecessarily and unwisely.

Given the enormous benefits in saved lives, improved outcomes, and decreased medical costs of early and rapid adoption of EHR systems, CMS should not write a pre-interoperability rule that is narrower than the post-interoperability rule, except to the extent needed to prevent patient and program abuse related to the lack of interoperability standards.

A. Eliminate Unnecessarily Restrictive Definitions and Uses of EHR

We incorporate all of the comments on the post-interoperability rule into our concerns regarding the pre-interoperability rule, in those areas in which both the post-interoperability rule and the pre-interoperability rule are not permissive enough to meet the policy objectives behind widespread adoption of EHR. Additionally, we are concerned about aspects of the pre-interoperability rule that are narrower than the post-interoperability rule in the following areas.

1. Eliminate the "Used Solely" Language in § 411.357(w).

We believe the "necessary and used solely" language in the pre-interoperability rule should be abandoned, for the same reasons we discussed above with regard to the word "necessary" (*see* Section II.A.3.), CMS does not explain why it is proposing to carry over the "used solely" language from the e-prescribing rule to the pre-interoperability rule, and we are not aware of a good reason for doing so. CMS can adequately protect against program abuse related to donations being used to support functions unrelated to EHR by requiring that the donations are "used in connection with" EHR functions.

2. Revise the Restrictive "Takes into Account" Volume or Value Limitation in § 411.357(w)(4).

The failure to have more donor-friendly "volume or value" language, as described in our discussion of the post-interoperability rule (*see* Section II.C.), is the primary reason some of the sponsors of this letter do not intend to make any pre-interoperability donations unless the final pre-interoperability rule is broadened. As good stewards of limited funds for EHR donations, we need to be able to target donations to physicians with whom we share the most patients or on the other factors discussed above. We do not see any risk of program abuse pre-interoperability that would not also be present post-interoperability, and the rules thus should be identical.

3. Avoid the Exclusion of "Any" Administrative Software in §411.357(w)(8).

This language is not present in the post-interoperability standard. While we do not oppose exclusion of administrative software from the protection of these rules, as discussed above (*see* Section II.A.1.), the ability to include a patient portal, which includes some scheduling software, is important to some potential donors. The fact that EHR software has some coding functionality built-in also concerns us under this restrictive language. We urge CMS to adopt the same approach in the pre-interoperability standard as we have advocated above post-interoperability. This restriction is another reason why some of the sponsors of this letter will take a wait and see approach until the post-interoperability rule is adopted or an expanded pre-interoperability rule is finalized.

B. Maintain Conditions that Prevent Program Abuse in the Pre-Interoperability Rule

We fully support the open use requirement in § 411.357(w)(2) and believe it goes a long way toward addressing CMS's concerns about program abuse in the pre-interoperability era. Further, in the post-interoperability discussion, we emphasize the importance of protecting technical support, including technical support that would allow an entity to evaluate whether a physician's existing EHR system (which may have been donated by another entity) can effectively communicate with the donor's system or with a community health information network (*see* Section II.A.2.). We believe this should also be applied to the pre-interoperability rule, and would reduce the likelihood of stand-alone systems or of non-technological barriers to connections between systems.

To further address CMS's concern about program abuse pre-interoperability, we would support an additional condition that would require donated EHR software to be subject to contract terms that require that it will be updated or upgraded to meet interoperability standards within some reasonable time after they are adopted. While donors could not guarantee that the vendors who make such promises will actually be able to succeed in making the donation interoperable, we expect that most vendors will both accept such language (because many are doing it now) and will in fact comply (because otherwise they will go out of business due to inability to sell their product).

We believe the conditions suggested above are sufficient to protect against reasonable concerns with program abuse pre-interoperability. Otherwise, the CMS exceptions should be identical pre and post interoperability, with both written to reflect the considerations discussed above with regard to the post-interoperability rule.

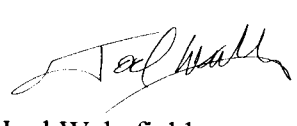
IV. Conclusion

The sponsors of this comment have a wealth of experience with implementing EHR and struggle with the challenges of making EHRs more effective in improving the quality of patient care. Despite the challenges and occasional setbacks, we are excited by the potential of EHR systems to fundamentally transform patient care.

These proposed rules are exceptionally important to our ability as potential donors to encourage the adoption of EHR, wholly without regard to the impact on referrals. We do not expect any of our donations of EHR software or support to affect the volume of referrals we receive, except to the extent that those referrals are more likely to be subject to clinical protocols and alerts and to scheduling for needed tests and services. None of the changes in referrals will be directly related to the donation of EHR to induce referrals. Any change in referrals will be due to improvements in care made possible by EHR.

If it would be useful to CMS to discuss details of how EHR systems work "on the ground," to understand the contracting process or the need for constant technical support, or to gain insight into any aspect of EHR adoption, please contact us. We have years of hands-on experience and are eager to share it in order to improve CMS's proposed EHR exceptions to the Stark self-referral law. Thank you for your consideration of our comments.

Sincerely,



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CMS-1303-P-19 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Ms. Kelly Lavin **Date & Time:** 12/12/2005

Organization : American Osteopathic Association

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1303-P-19-Attach-1.DOC

AMERICAN OSTEOPATHIC ASSOCIATION

1090 Vermont Avenue NW, Suite 510, Washington D.C. 20005 202 414 0140 | 800 962 9008

December 12, 2005

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

Via: http://www.cms.hhs.gov/regulations/ecomments

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 (10/11/05 Federal Register)

Dear Dr. McClellan:

Thank you for the opportunity to provide comments on physician self-referral exceptions for certain electronic prescribing (e-Rx) and health information technology (HIT) arrangements. The American Osteopathic Association (AOA), which represents the nation's 56,000 osteopathic physicians practicing in 23 specialties and subspecialties, appreciates ongoing efforts to develop and implement HIT.

The AOA is working to ensure that physicians have the ability to afford new health technologies. Physicians, especially those in small practices, face financial difficulties with funding their own technologies. Providing an exception under the Stark law for certain non-monetary remuneration related to e-prescribing information technology items and services would help greatly to break down the monetary barrier that prevents technology adoption. We were pleased with how quickly this proposed rule was released.

The rapid development of medical informatics is changing the face of the health care delivery system. It is imperative that these technological advances occur through a deliberative process in which physicians and other interested parties are able to provide input and ultimately shape the end product. If done with careful deliberation and consideration for the various issues that arise, e-prescribing and HIT have the potential to be a driving force in enhancing the quality and efficiency of the health care delivery system.

According to a 2004 Health Affairs study, more than half of all practicing physicians are in practices of three or fewer physicians. Three-quarters are in practices of eight or fewer. They face the same economic barriers as every other small business in America. Costs associated with staff salaries; health and other benefits, basic medical supplies, and technology, all essential components of any business, continue to rise at a rate that far outpaces reimbursements. Therefore, financial incentives must be created to offset the cost of initial investment in health information technology, particularly for physicians and other health care providers practicing in lower income, rural and underserved areas.

Our comments to the proposed rule are as follows:

II. PROVISIONS OF THE PROPOSED RULE
A. Electronic Prescribing Exception: § 411.357(v)
1. Protected Non-Monetary Remuneration
b. "Used Solely"

The AOA recognizes that the Act "requires that the protected items and services be used solely to transmit or receive electronic prescribing information". However, in upholding the goal to achieving interoperable health care information systems, we cannot build silos regionally, by state, by health care entity, and most certainty not by individual physician offices. In today's technology arena, software serves more than one purpose. Bundling several applications into one software package (such as office management tools, billing, scheduling, etc) usually saves money and promotes efficiency.

The AOA applauds your proposal to create "an additional exception for multi-functional hardware (including necessary operating system software) or connectivity services." Many physicians prefer to use single multi-functional devices, rather than multiple single-use devices. For that reason, when trying to entice more physicians to use e-Rx and other forms of HIT, the usability of the tools should be taken into account. If not, physicians may not want to be burdened by using several devices.

II. PROVISIONS OF THE PROPOSED RULE
A. Electronic Prescribing Exception: § 411.357(v)
2. Designated Health Services (DHS) Entities Protected by the Exception

The AOA feels that a group practice should be protected under the exemption to provide qualifying electronic prescribing technology to a physician in the group practice, if it chooses. In addition, we also support the decision of the Centers for Medicare and Medicaid Services (CMS) to use its authority to protect other DHS entities, which want to provide electronic prescribing technology to physicians as well. These two additions (group practices and other DHS entities) to the normal DHS entities can increase the options for physicians seeking assistance in establishing their own e-Rx capabilities. As for addressing which types of DHS entities should be included, we feel, if an entity wants to provide assistance, it should be allowed. However, without hindering the quality of patient care.

II. PROVISIONS OF THE PROPOSED RULE
B. Exceptions for Certain Arrangements Involving Electronic Health Records Items and Services: §411.357(w) and §411.357(x)
1. Pre-Interoperability Exception
a. Covered Technology

As stated previously in this document, more than half of all practicing physicians are in practices of three or fewer physicians. Three-quarters are in practices of eight or fewer. They face the same economic barriers as every other small business in America. Many of these physicians don't have established hardware and connectivity services in place to accommodate an e-Rx component. It is unfair to these providers not to be able to benefit from this proposed rule. We hope that certain exceptions will be made for rural providers, along with those practicing in lower income and underserved areas, so hardware and connectivity can be given for the purpose of using e-Rx.

The AOA urges CMS to use caution in the drafting of a formal definition of "electronic health record." There are various definitions of electronic health records and many opinions on what should and should not be included. Currently, such bodies as the American Health Information Community are looking into this issue. Please uphold a consensus of what is now classified as an electronic health record by most vendors and entities.

II. PROVISIONS OF THE PROPOSED RULE
B. Exceptions for Certain Arrangements Involving Electronic Health Records Items and Services: §411.357(w) and §411.357(x)
1. Pre-Interoperability Exception
d. Value of Protected Technology

The AOA discourages a monetary cap that would impose on the value of the donated multi-functional hardware or connectivity services. A cap would be difficult to formulate a specific dollar amount. For example, would the value be calculated by the donor's actual cost or the value it brought to the physician? In addition, a cap could unnecessarily discourage donors from providing items and services.

CONCLUSION
The AOA believes that one of the fundamental principles of patient centered quality care is the ability of patients to have access to appropriate drug therapies and other procedures. We realize controlling costs and implementing electronic prescribing and other health care technologies are important factors. However, access to appropriate treatments must be the primary focus. We hope that as CMS develops its policies on e-prescribing and other HIT initiatives, the focus will be ensuring access to appropriate treatments while improving the quality of patient care and safety.

The AOA appreciates the opportunity to comment on the proposed physician self-referral exceptions. We look forward to working with CMS in the future on this and other issues of concern to the osteopathic medical profession. If you have any questions, please contact Kelly Lavin, AOA Regulatory Policy Analyst, at 202-414-0140 or klavin@osteopathic.org.

Sincerely,

Philip L. Shettle, DO
AOA President

CC: President-Elect, AOA
Members, Board of Trustees, AOA
Chairman, Department of Government Affairs, AOA
Chairman and Members, Council on Federal Health Programs, AOA
Executive Director, AOA

CMS-1303-P-20 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Dan Rode **Date & Time:** 12/12/2005

Organization : American Health Information Management Association

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1303-P-20-Attach-1.DOC

CMS-1303-P-20-Attach-2.DOC

AHIMA
American Health Information Management Association®

December 9, 2005

Mark B. McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1303-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: RIN 0938-AN69
File Code CMS-1303-P

Dear Dr. McClellan:

On behalf of 50,000 professional health information management (HIM) members, the American Health Information Management Association (AHIMA) welcomes this opportunity to comment on the Center for Medicare and Medicaid Services' (CMS) proposed rule to create exceptions to existing regulations in order to permit the sharing of electronic prescribing (e-Rx) and electronic health records (EHRs) with physician offices, as described in the October 11, 2005 *Federal Register* (70FR59182). AHIMA welcomes CMS' attempt to modify existing Medicare self-referral regulations in order to support efforts by the healthcare industry and the Department of Health and Human Services (HHS/Department) to support eRx and develop a standard EHR and a nation wide health information network leading to interoperable health information, to serve the patient and the population.

AHIMA is a 77-year-old professional association representing more than 50,000 educated and certified HIM professionals who work throughout the healthcare industry. HIM professionals serve the healthcare industry and the public by managing, analyzing, and utilizing data vital for patient care and making it accessible to healthcare providers, plans, researchers, and other appropriate parties where and when it is needed most. AHIMA members are active in a variety of healthcare sites and organizations leading the conversion from the paper healthcare record to the standard EHR and working with the industry and the HHS Secretary and Department to see the establishment of an interoperative nation wide health information network (NHIN).

AHIMA is supportive of CMS and HHS' desire to further our electronic health information goals with these October 11 proposed rules. We have reviewed your proposal and made our comments from the perspective of a profession that manages health information and serves as the custodian of such information. Furthermore as noted, HIM professionals are deeply involved in the transformation of the healthcare industry from paper to electronic-based information and are active in multiple efforts to see the achievement of a standard electronic health record (EHR) and full interoperability as soon as possible.

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COMMENTS TO OCTOBER 11, 2005 PROPOSED RULE

General Comments

While AHIMA commends CMS and the Department's efforts to support the goals noted above, it is clear that the self-referral regulations as they are currently written, and these proposed rules do not fully acknowledge the current state of the healthcare industry.

The proposed regulations are narrow in their focus and presume that only hospitals or health systems may be in a position to provide electronic prescribing (eRx) or EHR components to physician practices or similar entities. In fact, such items, along with a variety of support elements including connectivity, software, technical support, training, and so forth could come from a variety of entities including health plans and similar organizations, possibly even those contracted with CMS to deliver a number of products associated with the Medicare or Medicaid programs. Any regulations written at this time should take into account the potential for a wide variety of entities to supply a variety of eRx or EHR components to physician practices and similar provider entities.

It is clear that authority for the proposed regulations is taken from Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act 2003 (MMA), and Section 1877 (b) (4) of the Social Security Act. We note that the former was written in 2003 and makes presumptions that are not reflective of the current environment, while the authority from the Social Security Act, used under the latter part of the proposed rule, is not used broadly enough to encourage and support the use of both eRx and EHR. AHIMA recommends that CMS and HHS, including the Office of the National Coordinator for Health Information Technology (ONC) and the American Health Information Community (the Community or AHIC) reconsider the approach to providing exceptions to the self-referral regulations in light of today's environment and the roles and goals of the Community and ONC. Only through such coordination can the industry hope to achieve the President's goals for interoperability by 2014 and eRx by 2008.

It is also appropriate to note that the proposed anti-kickback safe harbor regulations, being proposed simultaneously with these proposed regulations, takes an even narrower view. While enforcement of the self-referral and anti-kickback regulations has identified and prosecuted significant levels of fraud in the healthcare industry, such enforcement has also created a fear of stepping out of line even for legitimate purposes. If the two proposed rules cannot be modified to coordinate restrictions on providing or donating eRx and EHR devices, software, communication, support and training across the healthcare industry, then the fear of noncompliance will serve as a significant barrier to any progress the industry can make to improve quality, reduce injury, and achieve interoperability. Therefore, as the industry and various groups such as CMS, HHS, ONC AHIC and the Congress consider means to assist progress, the Office of the HHS Inspector General (OIG) and similar agencies must be involve in coordinating these regulations as proposed by CMS and the OIG.

Your proposed rule is written essentially in three parts: eRx, EHR "pre-Interoperability Exception," and EHR "post-Interoperability Exception." AHIMA is concerned with this three-part approach and the limited flexibility displayed in the regulations that could cause problems in the future:

- While we understand the MMA eRx is an important consideration for CMS, however, the assumptions for current relationships between eRx and electronic health records and eRX and a standard EHR, is not reflective of the existing environment. eRx and similar prescribing functions exist in a variety of relationships and combinations with other electronic software, and the

regulations suggested by CMS does not reflect these combinations in today's healthcare environment.

- AHIMA has led the establishment of a certification commission and the process of certifying health information technology (HIT). Because of the involvement of our members and staff in this work, we understand the intent of the regulation, pre and post, as proposed. Unfortunately, we do not believe that many in the industry currently understand the role and position of the commission and we doubt that this "pre and post" approach makes much sense to them. Since the timetables for this regulation and for the standards and the criteria it addresses are not known, we recommend that CMS consider writing the regulation from the perspective of "pre-Interoperability Exception" and not address the "post" era until sometime in the future. We also suggest the regulation state, however, the intention of CMS and HHS to revise the regulations in the future to take into account the development and adoption of standards and product criteria. This will keep the industry and its vendors fully informed of the Department's intention and will keep all aware of the need to produce products that will assist the industry in meeting its needs and its goals.

- We noted the rapid development and change going on in the healthcare industry and HIT. We believe these regulations should be written to acknowledge change as well. CMS has a variety of internal HHS and industry advisors that can provide a sense of the change. Regulations should be written, whenever possible to allow adjustment for change and not have to be rewritten periodically. While we are sure the "pre and post" process was an attempt to do this, our concern is directed more toward assumptions of what software packages will look like, as well as healthcare delivery structure.

The original self-referral or Stark laws were written to address and prevent fraud. These proposed rules are written with a strong assumption that movement toward eRx, and adoption and use of an EHR will accelerate fraudulent practices and raise the cost of healthcare. AHIMA is well aware of the fraud issue and we have addressed this concern in a couple of studies conduced under the auspices of the ONC, namely: *Use of Health Information Technology to Enhance and Expand Health Care Anti-fraud Activities* and *Automated Coding Software: Development and Use to Enhance Anti-Fraud Activities.* (See: http://www.ahima.org/fore/programs/research.asp)

AHIMA believes that the appropriate adoption of a standard EHR and other health information standards will decrease the potential for fraud. Many organizations, including the Institute of Medicine (IOM) and CMS have also pointed out that eRx and the EHR lead to improved quality, reduced injury, and other outcomes that reduce the cost of healthcare. While AHIMA applauds several positive items in the proposed rule to eliminate fraud, we are concerned that aspects of the rule where attempts to ascertain value and costs of donations, for the purpose of fraud protection, will become barriers to adoption or a reduction on the return on investment for eRx and the EHR.

In the "Covered Technology" section (70FR59188 – center column) you announce that you are considering including in the final regulations "a definition of 'electronic health records' for purposes of the exception." AHIMA is very concerned with this attempt especially in light of current work underway to consider the legal and business definition of an "electronic health record." We are not in a position to make a recommendation to CMS with regard to a definition at this time and we are not sure that it is a definition of the EHR that CMS should be considering; rather you should be considering elements of a standard EHR in line with activities of groups like the Commission for Certification of Electronic Health Records (CCHIT), Health Level Seven (HL7), and so forth. This

progress will take time. AHIMA is active in a number of these issues and projects and would like to work with CMS and HHS on this issue, before it is considered so narrowly.

"Necessary" Non-Monetary Remuneration

- AHIMA concurs it is not in CMS' best interest to sanction or provide duplication in the introduction of HIT hardware, software, and so forth in the same practice. However, while the industry is moving to standardization, most physician offices and many other entities are incapable of determining the extent to which a device or software may be duplicative of a part of some other device or software. (One commenter suggested that this was akin to having the average household determine how many remote-control devices were really needed for various media and manufacturers.). Accordingly, we do not believe that most physician offices, or other similar healthcare entities, are capable of certifying that items and services provided are not technically or functionally equivalent to those already possessed by the physician.

- AHIMA members also note that eRx, is in many cases, software that may exist in a larger domain of an electronic medical record. Therefore this potential regulation becomes a problem if the newly introduced device or software duplicates a part of previously acquired software. Physician offices or other groups should not have to worry about such situations, especially in this age of rapidly developing and evolving software.

- AHIMA members also point out that a physician office could have a relationship with a hospital, but then as part of a local or regional health information exchange, have a second relationship that might require the practice initially to have more than one piece of software. This is somewhat similar to hospitals which in the past had a different computer terminal in order to send different health plans exactly the same information. With standards this will change and improve, but the industry has not reached the use of such standards combined with application software at this time.

- Members note that physician offices are very concerned with potential violations of the anti-kickback and self-referral regulations and will avoid situations that provide potential risk to their practice. Our fear is that a requirement, such as this, may cause physician practices to avoid participation in the information exchange or cause them to limit such exchange to with one partner, which negates the goal of interoperability.

- Except for large practices already invested in HIT, our members do not see many practices that invested heavily who would then divest in favor of shifting costs to the designated health services (DHS) entity. We are aware that while there are a few DHS entities that can afford such a shift, the majority of health provider entities do not have the capital to do so and if they have spent the time to develop and use such software, their preference would usually be to keep it. While this does not suggest that inappropriate activities might not occur, we believe that an accounting of such sharing by the DHS entity should be required and could be audited. Meanwhile, let's not forego the opportunity to reach our goals for appropriate information sharing and recognize the potential administrative savings that will benefit the industry as a whole.

"Used" Solely

Substantial

- CMS recognizes that a device may be used for more than one function and software may be bundled and can perform more than one function. This is today's HIT reality. We are concerned, however, with the use of the term "substantial use" as it applies in this section of the proposed rule. At what level is "substantial use?" Does it only apply to Medicare patients? Is it describing use for a week, a month, a year? How will a physician's office account for use? Could the accounting become such a burden that it is better to not use the device or software? MMA's goal was in part to lower the error or injury rate associated with prescriptions. We believe that the overall goal is the interoperable exchange of health information to better serve the patient and the population, and this implementation will also result in cost savings. As long as the device or software supports these goals, we do not believe it is in the best interest of the nation to develop an accounting for the volume use of such devices or software.

- The need for a cap on the nature and amount of expenditures provided to physician practices and similar entities is understandable, but we don't know how such a cap can be determined given the nature and growth of HIT. Such values change rapidly and vary across the country and the industry. A device or software that might cost $2,000 today may only cost $600 six months from now. Costs vary by what's in a product and other vendor factors and, as the proposed regulation notes, there may be some single-use devices. But, there will also be multi-functional devices and both might be appropriate. If an institution wants to share devices, software, and so forth and can meet some of the requirements that should remain in the rule, then we believe that healthcare profits are weak enough, and physician's desire for independence is strong enough that developing caps and similar data should take an hiatus.

Designated Health Services (DHS) Entities Protected by the Exception

- AHIMA believes that all DHS entities should be included in the rule and not just hospitals or health networks. To benefit from interoperability or even from just prescription information could result in information exchange beyond that currently listed by CMS. For instance, the function of prescribing should also take into consideration medication histories, laboratory results, and so forth, not just the function of writing and transferring the prescription itself. The long-term goal of improving health, reducing risk, and achieving interoperability and administrative savings is not served by limiting these exceptions to just hospitals. CMS and the Department should broaden its approach to achieve the maximum potential for these goals and not keep itself in the boundaries of healthcare delivery in the 1980s and 1990s.

Promoting Compatibility and Interoperability

- This is an important issue. AHIMA agrees with the department that HHS and the industry should be promoting compatibility and interoperability. We acknowledge the statement that technology must be in accordance with standards, and not all the standards necessary for full interoperability exist today. We further agree with the CMS that these regulations should promote an environment that is more than just the sending and receiving of electronic prescription information and as such could and should cover other services, orders, and so forth. AHIMA agrees with the concepts identified in the definition suggested in this section (70Fr59186), but we must note that to be truly interoperable, the industry must also come to agreement on the uniform definition and terms that

are exchanged in the systems, applications, and networks described here. To date HHS has fallen short in this arena and CMS continues to support an environment where multiple data elements or codes have been developed that carry the same definition.

Value of Protected Technology

- AHIMA understands CMS' concern with capping the amount of items and services provided under the proposed protections. We can only reiterate that arriving at such caps and then applying them to software or devises that may or may not have exclusivity of function or role will be very difficult and hamper forward progress. As noted, the costs of such items – software, support services, training and so forth will vary by region, size of the supplying organization (that may have access to discounts that others may not have), and so forth. We sympathize with the problem this creates for CMS, but believe that it should be judged in the context of the total goal of interoperability and not just that of eRx.

Other Conditions

- We agree with the conditions listed in Section 411.357 (v) except for:
  - (1) – Too limited on the providers and receivers of such items, support, and services
  - (7) (ii) – While the items or services being provided should be specified in an agreement, it must be noted that the value of such is not consistent and should not be used alone to determine any violation of the regulation.
  - (7) (iv) – this requires a certification by the physician on equivalency of technology or functionality, we do not believe most physician offices, or many others are capable of making such a certification.
  - (8) – similar to 7 (iv), this requires knowledge not generally possessed by the entity or the physician.

- Sections 411.357 (w) and (x) are similar to (v) and we have noted above our concerns on a pre and post set of requirements.
  - We must note that (w) (9) calls for knowledge that "the electronic health records technology contains 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." It is not clear who pre-CCHIT would certify in this case – the provider or the vendor?

- We agree that an item or devices should be functional for all patients and with all potential exchange (prescription, supply orders, and so forth) partners, assuming the use of uniform standards. Accordingly, where and when uniform standard exist, have been harmonized, and certified, we agree it is improper to offer devices or items, under the protection of these proposed regulation, that do not meet these criteria.

Covered Technology

- While AHIMA has noted that some current electronic medical record systems include a form of eRx, it is not appropriate to assume that all eRx systems should be or are part of an EHR product or item bundle.

- Regulation should not make any assumptions that a particular component of an EHR should or should not be able to perform the same functions, pre-certification. When standards are applied, and product criteria are developed, then, at some point, an entity should be required to send or receive transactions according to the uniform standard. We disagree with the concept of requiring computerized provider order entry (CPOE) as a component of an EHR, as proposed on 70FR59188, at this time. Likewise, while we realize that CMS might want to exclude software that includes, say an electronic billing system. But, it must recognize that such exclusion could become a barrier to a physician office or other group whose software combines such a function with that of eRx or some functions of an electronic record.

- As noted above, AHIMA is concerned with CMS developing a definition of the EHR in these regulations. However, we recognize that what CMS wants to do is determine functions that may be part of an EHR so as to determine software packages, devices, telecommunications needs, support, training and so forth that should be identified in these regulations. Since the AHIMA, HL7 and others are working in this area, we recommend that designating such software packages not be done until more work is complete and the certification commission has designated appropriate criteria.

Standards with Which Donated Technology Must Comply

- AHIMA agrees that any donated or shared software should meet the standards established by the Secretary. However, we must also note that there will be a period of implementation before any compliance date is reached, and it should be clear that the standards requirement or any criteria requirement will only become required, after the appropriate compliance date, presuming the parties or entities involved are covered by that standard requirement.

- The proposed regulation also notes consideration of requiring protected software to comply with relevant Public Health Information Network preparedness standards, such as those related to BioSense. These standards have not been made a requirement by the Secretary on Medicare providers or other providers in the healthcare industry to our knowledge. Therefore, unless CMS intends to make this part of the Medicare Conditions of Participation and institutes a standard transaction for the transmission of such data, we believe such a requirement is premature. In making this recommendation, AHIMA acknowledges that it fully expects to support population health report data as part of eventual standards and criteria associated with either the EHR or the NHIN.

Permissible Donors

- AHIMA understands that CMS is only attempting to identify those entities covered under the current self-referral regulation. However, given the authority provided by the Act, we recommend expanding the donors, as recommended above, in order to stimulate the adoption of eRx and EHR. We note that the assumption made on ancillary providers not being positioned to advance the goal of interoperable EHRs is not our experience. The benefits of adopting interoperable eHRs are not limited to improving the quality of care, but also to improving the efficiency of health care that translate into economic savings. Third party payers, such as CMS, will directly benefit from the economies resulting from the use of interoperable EHRs. A reduction in duplicative testing, more timely communication, and the sharing of information between providers will drive the economies. Everyone that has a stake in the potential for administrative efficiency and savings. Therefore,

establishment of local and nation-wide health information networks suggests that donors should not be necessarily limited to their constituencies.

Selection of Recipients

- AHIMA agrees that certified, interoperable systems will offer enhanced protection against some types of fraud and abuse. We understand that for this reason CMS is proposing to permit donors to use selective criteria for choosing recipients. We have agreed that CMS' criterion in a post-certification environment is reasonable and a donor should be able to demonstrate the rational behind a donation. AHIMA suggests, however, that just as we have noted a reason to expand permissible donors, there should also be capability for a donor to expand the potential list of recipients. Our rationale for this suggest merely is based on the potential for a donor to be willing to donate to unrelated recipients in a local information network, because economically it is capable of doing so and recognizes the benefits to the community. Since the entire community benefits from a fully functioning network, stakeholders in the network should be permitted to help each other.

Conclusion

The healthcare industry, the federal government, and most of all the patient/consumer/citizen will all benefit from the implementation and utilization of eRx, a standard EHR, and nation wide interoperability. The members of AHIMA applaud CMS and the Department's desire to provide changes to the self-referral regulations to promote the sharing of eRX, and EHR-related devices, software, training and other related resources. AHIMA understands the concerns that CMS has that such sharing could be abused, but suggests that the benefits of interoperability be balanced against this risk. In our comments above, AHIMA suggests ways to meet such a balance. The environment is changing rapidly and regulations must be designed to keep-up with and promote advancement not become a barrier.

AHIMA and its 50,000 member professionals are working hard to see the achievement of this nation's interoperable goals. We hope these recommendations will assist CMS in this effort and we stand ready to work with CMS and the Department in any way possible to achieve our common goal. If there are any questions regarding these comments and recommendations, or if there is any way that AHIMA might assist the Department, please contact me, at (202) 659-9440 or dan.rode@ahima.org. We thank you again for your efforts to achieve our common goal and for this opportunity to provide input to your proposed regulation.

Sincerely,

Dan Rode, MBA, FHFMA
Vice President, Policy and Government Relations

AHIMA
American Health Information Management Association®

December 9, 2005

Mark B. McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1303-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: RIN 0938-AN69
File Code CMS-1303-P

Dear Dr. McClellan:

On behalf of 50,000 professional health information management (HIM) members, the American Health Information Management Association (AHIMA) welcomes this opportunity to comment on the Center for Medicare and Medicaid Services' (CMS) proposed rule to create exceptions to existing regulations in order to permit the sharing of electronic prescribing (e-Rx) and electronic health records (EHRs) with physician offices, as described in the October 11, 2005 *Federal Register* (70FR59182). AHIMA welcomes CMS' attempt to modify existing Medicare self-referral regulations in order to support efforts by the healthcare industry and the Department of Health and Human Services (HHS/Department) to support eRx and develop a standard EHR and a nation wide health information network leading to interoperable health information, to serve the patient and the population.

AHIMA is a 77-year-old professional association representing more than 50,000 educated and certified HIM professionals who work throughout the healthcare industry. HIM professionals serve the healthcare industry and the public by managing, analyzing, and utilizing data vital for patient care and making it accessible to healthcare providers, plans, researchers, and other appropriate parties where and when it is needed most. AHIMA members are active in a variety of healthcare sites and organizations leading the conversion from the paper healthcare record to the standard EHR and working with the industry and the HHS Secretary and Department to see the establishment of an interoperative nation wide health information network (NHIN).

AHIMA is supportive of CMS and HHS' desire to further our electronic health information goals with these October 11 proposed rules. We have reviewed your proposal and made our comments from the perspective of a profession that manages health information and serves as the custodian of such information. Furthermore as noted, HIM professionals are deeply involved in the transformation of the healthcare industry from paper to electronic-based information and are active in multiple efforts to see the achievement of a standard electronic health record (EHR) and full interoperability as soon as possible.

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COMMENTS TO OCTOBER 11, 2005 PROPOSED RULE

General Comments

While AHIMA commends CMS and the Department's efforts to support the goals noted above, it is clear that the self-referral regulations as they are currently written, and these proposed rules do not fully acknowledge the current state of the healthcare industry.

The proposed regulations are narrow in their focus and presume that only hospitals or health systems may be in a position to provide electronic prescribing (eRx) or EHR components to physician practices or similar entities. In fact, such items, along with a variety of support elements including connectivity, software, technical support, training, and so forth could come from a variety of entities including health plans and similar organizations, possibly even those contracted with CMS to deliver a number of products associated with the Medicare or Medicaid programs. Any regulations written at this time should take into account the potential for a wide variety of entities to supply a variety of eRx or EHR components to physician practices and similar provider entities.

It is clear that authority for the proposed regulations is taken from Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act 2003 (MMA), and Section 1877 (b) (4) of the Social Security Act. We note that the former was written in 2003 and makes presumptions that are not reflective of the current environment, while the authority from the Social Security Act, used under the latter part of the proposed rule, is not used broadly enough to encourage and support the use of both eRx and EHR. AHIMA recommends that CMS and HHS, including the Office of the National Coordinator for Health Information Technology (ONC) and the American Health Information Community (the Community or AHIC) reconsider the approach to providing exceptions to the self-referral regulations in light of today's environment and the roles and goals of the Community and ONC. Only through such coordination can the industry hope to achieve the President's goals for interoperability by 2014 and eRx by 2008.

It is also appropriate to note that the proposed anti-kickback safe harbor regulations, being proposed simultaneously with these proposed regulations, takes an even narrower view. While enforcement of the self-referral and anti-kickback regulations has identified and prosecuted significant levels of fraud in the healthcare industry, such enforcement has also created a fear of stepping out of line even for legitimate purposes. If the two proposed rules cannot be modified to coordinate restrictions on providing or donating eRx and EHR devices, software, communication, support and training across the healthcare industry, then the fear of noncompliance will serve as a significant barrier to any progress the industry can make to improve quality, reduce injury, and achieve interoperability. Therefore, as the industry and various groups such as CMS, HHS, ONC AHIC and the Congress consider means to assist progress, the Office of the HHS Inspector General (OIG) and similar agencies must be involve in coordinating these regulations as proposed by CMS and the OIG.

Your proposed rule is written essentially in three parts: eRx, EHR "pre-Interoperability Exception," and EHR "post-Interoperability Exception." AHIMA is concerned with this three-part approach and the limited flexibility displayed in the regulations that could cause problems in the future:

- While we understand the MMA eRx is an important consideration for CMS, however, the assumptions for current relationships between eRx and electronic health records and eRX and a standard EHR, is not reflective of the existing environment. eRx and similar prescribing functions exist in a variety of relationships and combinations with other electronic software, and the

regulations suggested by CMS does not reflect these combinations in today's healthcare environment.

- AHIMA has led the establishment of a certification commission and the process of certifying health information technology (HIT). Because of the involvement of our members and staff in this work, we understand the intent of the regulation, pre and post, as proposed. Unfortunately, we do not believe that many in the industry currently understand the role and position of the commission and we doubt that this "pre and post" approach makes much sense to them. Since the timetables for this regulation and for the standards and the criteria it addresses are not known, we recommend that CMS consider writing the regulation from the perspective of "pre-Interoperability Exception" and not address the "post" era until sometime in the future. We also suggest the regulation state, however, the intention of CMS and HHS to revise the regulations in the future to take into account the development and adoption of standards and product criteria. This will keep the industry and its vendors fully informed of the Department's intention and will keep all aware of the need to produce products that will assist the industry in meeting its needs and its goals.

- We noted the rapid development and change going on in the healthcare industry and HIT. We believe these regulations should be written to acknowledge change as well. CMS has a variety of internal HHS and industry advisors that can provide a sense of the change. Regulations should be written, whenever possible to allow adjustment for change and not have to be rewritten periodically. While we are sure the "pre and post" process was an attempt to do this, our concern is directed more toward assumptions of what software packages will look like, as well as healthcare delivery structure.

The original self-referral or Stark laws were written to address and prevent fraud. These proposed rules are written with a strong assumption that movement toward eRx, and adoption and use of an EHR will accelerate fraudulent practices and raise the cost of healthcare. AHIMA is well aware of the fraud issue and we have addressed this concern in a couple of studies conduced under the auspices of the ONC, namely: *Use of Health Information Technology to Enhance and Expand Health Care Anti-fraud Activities* and *Automated Coding Software: Development and Use to Enhance Anti-Fraud Activities.* (See: http://www.ahima.org/fore/programs/research.asp)

AHIMA believes that the appropriate adoption of a standard EHR and other health information standards will decrease the potential for fraud. Many organizations, including the Institute of Medicine (IOM) and CMS have also pointed out that eRx and the EHR lead to improved quality, reduced injury, and other outcomes that reduce the cost of healthcare. While AHIMA applauds several positive items in the proposed rule to eliminate fraud, we are concerned that aspects of the rule where attempts to ascertain value and costs of donations, for the purpose of fraud protection, will become barriers to adoption or a reduction on the return on investment for eRx and the EHR.

In the "Covered Technology" section (70FR59188 – center column) you announce that you are considering including in the final regulations "a definition of 'electronic health records' for purposes of the exception." AHIMA is very concerned with this attempt especially in light of current work underway to consider the legal and business definition of an "electronic health record." We are not in a position to make a recommendation to CMS with regard to a definition at this time and we are not sure that it is a definition of the EHR that CMS should be considering; rather you should be considering elements of a standard EHR in line with activities of groups like the Commission for Certification of Electronic Health Records (CCHIT), Health Level Seven (HL7), and so forth. This

progress will take time. AHIMA is active in a number of these issues and projects and would like to work with CMS and HHS on this issue, before it is considered so narrowly.

"Necessary" Non-Monetary Remuneration

- AHIMA concurs it is not in CMS' best interest to sanction or provide duplication in the introduction of HIT hardware, software, and so forth in the same practice. However, while the industry is moving to standardization, most physician offices and many other entities are incapable of determining the extent to which a device or software may be duplicative of a part of some other device or software. (One commenter suggested that this was akin to having the average household determine how many remote-control devices were really needed for various media and manufacturers.). Accordingly, we do not believe that most physician offices, or other similar healthcare entities, are capable of certifying that items and services provided are not technically or functionally equivalent to those already possessed by the physician.

- AHIMA members also note that eRx, is in many cases, software that may exist in a larger domain of an electronic medical record. Therefore this potential regulation becomes a problem if the newly introduced device or software duplicates a part of previously acquired software. Physician offices or other groups should not have to worry about such situations, especially in this age of rapidly developing and evolving software.

- AHIMA members also point out that a physician office could have a relationship with a hospital, but then as part of a local or regional health information exchange, have a second relationship that might require the practice initially to have more than one piece of software. This is somewhat similar to hospitals which in the past had a different computer terminal in order to send different health plans exactly the same information. With standards this will change and improve, but the industry has not reached the use of such standards combined with application software at this time.

- Members note that physician offices are very concerned with potential violations of the anti-kickback and self-referral regulations and will avoid situations that provide potential risk to their practice. Our fear is that a requirement, such as this, may cause physician practices to avoid participation in the information exchange or cause them to limit such exchange to with one partner, which negates the goal of interoperability.

- Except for large practices already invested in HIT, our members do not see many practices that invested heavily who would then divest in favor of shifting costs to the designated health services (DHS) entity. We are aware that while there are a few DHS entities that can afford such a shift, the majority of health provider entities do not have the capital to do so and if they have spent the time to develop and use such software, their preference would usually be to keep it. While this does not suggest that inappropriate activities might not occur, we believe that an accounting of such sharing by the DHS entity should be required and could be audited. Meanwhile, let's not forego the opportunity to reach our goals for appropriate information sharing and recognize the potential administrative savings that will benefit the industry as a whole.

"Used" Solely

Substantial

- CMS recognizes that a device may be used for more than one function and software may be bundled and can perform more than one function. This is today's HIT reality. We are concerned, however, with the use of the term "substantial use" as it applies in this section of the proposed rule. At what level is "substantial use?" Does it only apply to Medicare patients? Is it describing use for a week, a month, a year? How will a physician's office account for use? Could the accounting become such a burden that it is better to not use the device or software? MMA's goal was in part to lower the error or injury rate associated with prescriptions. We believe that the overall goal is the interoperable exchange of health information to better serve the patient and the population, and this implementation will also result in cost savings. As long as the device or software supports these goals, we do not believe it is in the best interest of the nation to develop an accounting for the volume use of such devices or software.

- The need for a cap on the nature and amount of expenditures provided to physician practices and similar entities is understandable, but we don't know how such a cap can be determined given the nature and growth of HIT. Such values change rapidly and vary across the country and the industry. A device or software that might cost $2,000 today may only cost $600 six months from now. Costs vary by what's in a product and other vendor factors and, as the proposed regulation notes, there may be some single-use devices. But, there will also be multi-functional devices and both might be appropriate. If an institution wants to share devices, software, and so forth and can meet some of the requirements that should remain in the rule, then we believe that healthcare profits are weak enough, and physician's desire for independence is strong enough that developing caps and similar data should take an hiatus.

Designated Health Services (DHS) Entities Protected by the Exception

- AHIMA believes that all DHS entities should be included in the rule and not just hospitals or health networks. To benefit from interoperability or even from just prescription information could result in information exchange beyond that currently listed by CMS. For instance, the function of prescribing should also take into consideration medication histories, laboratory results, and so forth, not just the function of writing and transferring the prescription itself. The long-term goal of improving health, reducing risk, and achieving interoperability and administrative savings is not served by limiting these exceptions to just hospitals. CMS and the Department should broaden its approach to achieve the maximum potential for these goals and not keep itself in the boundaries of healthcare delivery in the 1980s and 1990s.

Promoting Compatibility and Interoperability

- This is an important issue. AHIMA agrees with the department that HHS and the industry should be promoting compatibility and interoperability. We acknowledge the statement that technology must be in accordance with standards, and not all the standards necessary for full interoperability exist today. We further agree with the CMS that these regulations should promote an environment that is more than just the sending and receiving of electronic prescription information and as such could and should cover other services, orders, and so forth. AHIMA agrees with the concepts identified in the definition suggested in this section (70Fr59186), but we must note that to be truly interoperable, the industry must also come to agreement on the uniform definition and terms that

are exchanged in the systems, applications, and networks described here. To date HHS has fallen short in this arena and CMS continues to support an environment where multiple data elements or codes have been developed that carry the same definition.

Value of Protected Technology

- AHIMA understands CMS' concern with capping the amount of items and services provided under the proposed protections. We can only reiterate that arriving at such caps and then applying them to software or devises that may or may not have exclusivity of function or role will be very difficult and hamper forward progress. As noted, the costs of such items – software, support services, training and so forth will vary by region, size of the supplying organization (that may have access to discounts that others may not have), and so forth. We sympathize with the problem this creates for CMS, but believe that it should be judged in the context of the total goal of interoperability and not just that of eRx.

Other Conditions

- We agree with the conditions listed in Section 411.357 (v) except for:
  - (1) – Too limited on the providers and receivers of such items, support, and services
  - (7) (ii) – While the items or services being provided should be specified in an agreement, it must be noted that the value of such is not consistent and should not be used alone to determine any violation of the regulation.
  - (7) (iv) – this requires a certification by the physician on equivalency of technology or functionality, we do not believe most physician offices, or many others are capable of making such a certification.
  - (8) – similar to 7 (iv), this requires knowledge not generally possessed by the entity or the physician.

- Sections 411.357 (w) and (x) are similar to (v) and we have noted above our concerns on a pre and post set of requirements.
  - We must note that (w) (9) calls for knowledge that "the electronic health records technology contains 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." It is not clear who pre-CCHIT would certify in this case – the provider or the vendor?

- We agree that an item or devices should be functional for all patients and with all potential exchange (prescription, supply orders, and so forth) partners, assuming the use of uniform standards. Accordingly, where and when uniform standard exist, have been harmonized, and certified, we agree it is improper to offer devices or items, under the protection of these proposed regulation, that do not meet these criteria.

Covered Technology

- While AHIMA has noted that some current electronic medical record systems include a form of eRx, it is not appropriate to assume that all eRx systems should be or are part of an EHR product or item bundle.

- Regulation should not make any assumptions that a particular component of an EHR should or should not be able to perform the same functions, pre-certification. When standards are applied, and product criteria are developed, then, at some point, an entity should be required to send or receive transactions according to the uniform standard. We disagree with the concept of requiring computerized provider order entry (CPOE) as a component of an EHR, as proposed on 70FR59188, at this time. Likewise, while we realize that CMS might want to exclude software that includes, say an electronic billing system. But, it must recognize that such exclusion could become a barrier to a physician office or other group whose software combines such a function with that of eRx or some functions of an electronic record.

- As noted above, AHIMA is concerned with CMS developing a definition of the EHR in these regulations. However, we recognize that what CMS wants to do is determine functions that may be part of an EHR so as to determine software packages, devices, telecommunications needs, support, training and so forth that should be identified in these regulations. Since the AHIMA, HL7 and others are working in this area, we recommend that designating such software packages not be done until more work is complete and the certification commission has designated appropriate criteria.

Standards with Which Donated Technology Must Comply

- AHIMA agrees that any donated or shared software should meet the standards established by the Secretary. However, we must also note that there will be a period of implementation before any compliance date is reached, and it should be clear that the standards requirement or any criteria requirement will only become required, after the appropriate compliance date, presuming the parties or entities involved are covered by that standard requirement.

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Conclusion

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AHIMA and its 50,000 member professionals are working hard to see the achievement of this nation's interoperable goals. We hope these recommendations will assist CMS in this effort and we stand ready to work with CMS and the Department in any way possible to achieve our common goal. If there are any questions regarding these comments and recommendations, or if there is any way that AHIMA might assist the Department, please contact me, at (202) 659-9440 or dan.rode@ahima.org. We thank you again for your efforts to achieve our common goal and for this opportunity to provide input to your proposed regulation.

Sincerely,

Dan Rode, MBA, FHFMA
Vice President, Policy and Government Relations

CMS-1303-P-21 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Mr. J. Richard Cheney **Date & Time:** 12/12/2005

Organization : The Methodist Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1303-P-21-Attach-1.DOC

CMS-1303-P-21-Attach-2.PDF

December 12, 2005

Mark B McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Room 445-G
Washington, D.C. 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 Methodist Hospital ("TMH"), TMH Physician Organization ("TMHPO") and The Methodist Hospital Research Institute ("TMHRI") (collectively, the "TMH System") appreciate the opportunity to comment on the above referenced proposed rule outlining exceptions to the Physician Self Referral ("Stark") regulations.

With one exception, the TMH System concurs with the comments submitted to you by the American Hospital Association and the Texas Hospital Association. In addition to the issues raised in those letters, the TMH System submits the following comments:

Computerized Physician Order Entry

Although we generally agree with the comments submitted to you by the Texas Hospital Association, we have a different opinion regarding Computerized Physician Order Entry ("CPOE"). Specifically, we would like to see the regulations require CPOE to be included in EHR. CPOE is an effective method for reducing medication and other transcription errors, resulting in increased patient safety. In addition, CPOE is crucial to collection of information about test orders and maintenance of accurate flow of data and results. As a result, we agree with the American Hospital Association's comment that e-prescriptions should be an integrated piece of the full EHR, and it is our position that any e-prescription product should be required to have all the additional benefits offered by CPOE.

The Need for Centralized Databases

An issue that was not addressed in the proposed rules is the benefit of centralized databases of EHR data. In order for the federal government to achieve its stated goals of efficiency, continuity of care and cost-containment, it is absolutely necessary that the proposed rules require, whenever possible, centralized databases of EHR data. Such a

requirement will limit the difficulties posed by creating interfaces between different software programs and facilitate collaboration amongst health care providers.

Expand Definition of Permissible Recipients

In order to ensure continuity of care, the scope of permissible recipients of e-prescription and EHR software should be expanded to cover entities including, but not limited to, community clinics, home health care agencies and long term care facilities. This expansion of permissible recipients is necessary to ensure continuity of care for patients as they move through different levels of acuity.

Further, the regulations are unclear as to the circumstances under which a hospital may restrict to whom it provides electronic prescription and EHR software. We request that you provide more specific guidance on what defines a physician who "routinely furnishes services at the hospital." Also, if a hospital donates software to one member of its medical staff who routinely furnishes services at the hospital, must it make such a donation to all members of its medical staff who routinely furnish services at the hospital? Moreover, it is also beneficial to include as a permissible recipient any health care provider in a hospital who has a Medicare provider number (*e.g.*, physician assistants and nurse practitioners).

We also see real problems with the proposed rule that a member of a group practice who may r eceive a donation does not include an independent c ontractor or non-physician. Any health care provider in a group medical practice with a Medicare provider number should be permitted to receive a donation. Further, locum tenens providers and medical residents and/or fellows participating in rotations through group medical practices should have access to the donated software.

Expand Definition of Permissible Donors

The proposed regulations should expand the definition of permissible donors. For example, disease management programs or companies should be permissible donors, because they have an interest in communicating directly with healthcare providers, and there is as great deal of intrinsic good in the services they provide.

Limitations on Hardware

Although the donation of hardware is not addressed in the proposed regulations, during the C MS O pen F orum Conference C all r egarding t hese p roposed r egulatory changes, several participants noted that, should there be a time when donation of hardware is permissible, any equipment given to physicians for e-prescriptions or EHR would have to be used exclusively for that purpose. Not only do we believe that it should be permissible to donate hardware under the final regulations, but we also feel that the limitation on exclusive use will prove to be impractical, because the trend in technology is for convergence of equipment. Moreover, it will be important to use this hardware for multiple functions in order to improve efficiency of health care delivery.

Conclusion

We appreciate the opportunity to submit comments and express our concerns regarding the proposed rules. If we may be of further assistance in clarifying the TMH System's position or in making further suggestions for the final rules, please contact Mr. Cheney at (713) 441-4925 or DCHENEY@TMH.TMC.EDU. You may contact Dr. Samo at (713) 799-9997 or TSAMO@TMH.TMC.EDU.

Very truly yours,

J. Richard Cheney
Vice President, Legal Services
The Methodist Hospital

Tobias, Samo, M.D.
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December 12, 2005

Mark B McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
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Dear Dr. McClellan:

The Methodist Hospital ("TMH"), TMH Physician Organization ("TMHPO") and The Methodist Hospital Research Institute ("TMHRI") (collectively, the "TMH System") appreciate the opportunity to comment on the above referenced proposed rule outlining exceptions to the Physician Self Referral ("Stark") regulations.

With one exception, the TMH System concurs with the comments submitted to you by the American Hospital Association and the Texas Hospital Association. In addition to the issues raised in those letters, the TMH System submits the following comments:

Computerized Physician Order Entry

Although we generally agree with the comments submitted to you by the Texas Hospital Association, we have a different opinion regarding Computerized Physician Order Entry ("CPOE"). Specifically, we would like to see the regulations require CPOE to be included in EHR. CPOE is an effective method for reducing medication and other transcription errors, resulting in increased patient safety. In addition, CPOE is crucial to collection of information about test orders and maintenance of accurate flow of data and results. As a result, we agree with the American Hospital Association's comment that e-prescriptions should be an integrated piece of the full EHR, and it is our position that any e-prescription product should be required to have all the additional benefits offered by CPOE.

The Need for Centralized Databases

An issue that was not addressed in the proposed rules is the benefit of centralized databases of EHR data. In order for the federal government to achieve its stated goals of efficiency, continuity of care and cost-containment, it is absolutely necessary that the proposed rules require, whenever possible, centralized databases of EHR data. Such a

requirement will limit the difficulties posed by creating interfaces between different software programs and facilitate collaboration amongst health care providers.

Expand Definition of Permissible Recipients

In order to ensure continuity of care, the scope of permissible recipients of e-prescription and EHR software should be expanded to cover entities including, but not limited to, community clinics, home health care agencies and long term care facilities. This expansion of permissible recipients is necessary to ensure continuity of care for patients as they move through different levels of acuity.

Further, the regulations are unclear as to the circumstances under which a hospital may restrict to whom it provides electronic prescription and EHR software. We request that you provide more specific guidance on what defines a physician who "routinely furnishes services at the hospital." Also, if a hospital donates software to one member of its medical staff who routinely furnishes services at the hospital, must it make such a donation to all members of its medical staff who routinely furnish services at the hospital? Moreover, it is also beneficial to include as a permissible recipient any health care provider in a hospital who has a Medicare provider number (*e.g.*, physician assistants and nurse practitioners).

We also see real problems with the proposed rule that a member of a group practice who may receive a donation does not include an independent contractor or non-physician. Any health care provider in a group medical practice with a Medicare provider number should be permitted to receive a donation. Further, locum tenens providers and medical residents and/or fellows participating in rotations through group medical practices should have access to the donated software.

Expand Definition of Permissible Donors

The proposed regulations should expand the definition of permissible donors. For example, disease management programs or companies should be permissible donors, because they have an interest in communicating directly with healthcare providers, and there is as great deal of intrinsic good in the services they provide.

Limitations on Hardware

Although the donation of hardware is not addressed in the proposed regulations, during the CMS Open Forum Conference Call regarding these proposed regulatory changes, several participants noted that, should there be a time when donation of hardware is permissible, any equipment given to physicians for e-prescriptions or EHR would have to be used exclusively for that purpose. Not only do we believe that it should be permissible to donate hardware under the final regulations, but we also feel that the limitation on exclusive use will prove to be impractical, because the trend in technology is for convergence of equipment. Moreover, it will be important to use this hardware for multiple functions in order to improve efficiency of health care delivery.

Conclusion

We appreciate the opportunity to submit comments and express our concerns regarding the proposed rules. If we may be of further assistance in clarifying the TMH System's position or in making further suggestions for the final rules, please contact Mr. Cheney at (713) 441-4925 or DCHENEY@TMH.TMC.EDU. You may contact Dr. Samo at (713) 799-9997 or TSAMO@TMH.TMC.EDU.

Very truly yours,

J. Richard Cheney
Vice President, Legal Services
The Methodist Hospital

Tobias Samo, M.D.

Medical Director of Information Technology
The Methodist Hospital System

CMS-1303-P-22 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : **Mr. Robert Jasak** **Date & Time:** **12/12/2005**

Organization : **American Association of Orthopaedic Surgeons**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Issue

Background

See Attachment

Provisions of the Proposed Rule

See Attachment

CMS-1303-P-22-Attach-1.DOC

CMS-1303-P-22-Attach-1.DOC

CMS-1303-P-22-Attach-1.DOC

AAOS American Association of Orthopaedic Surgeons
3[illegible] Massachusetts Avenue NE 1st Floor Washington, D.C. 20002-5701
Phone 202/546-4430 Fax 202/546-5051 Internet www.aaos.org

December 12, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
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: 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

Dear Dr. McClellan:

The American Association of Orthopaedic Surgeons (AAOS) appreciates the opportunity to comment on the proposed rule on exceptions for electronic prescribing and electronic health records arrangements. In addition, AAOS thanks the Centers for Medicare and Medicaid Services (CMS) for holding the Open Door Forum on November 9, 2005 to discuss the self-referral and anti-kickback statute implications in the provision of health care information technology to physicians.

Given the proliferation and escalating costs of health care information technology, AAOS appreciates the efforts taken by CMS in the proposed rule. While we have concerns about specific provisions in the proposed rule, we generally agree that exceptions are necessary given that the anti-referral regulations often preclude relationships that would improve patient care and decrease health care costs. We appreciate these and other efforts to allow physicians to cooperate with other health care entities to ensure that the best available technology for improving patient safety and providing quality care is utilized.

Our first concern is general in nature and pertains to how we have heard the self-referral exceptions marketed, including the manner in which it was discussed on the Open Door Forum. We do not believe that this regulation is the panacea to address the lack of health

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care information technology, nor does it even address the major barrier to the proliferation of that technology. This regulation would remove a minor impediment to those few organizations that have the means to provide the "covered technologies." While this is a necessary step, we believe that CMS and the Department of Health and Human Services must play a much larger role in capitalizing the technologies that assist physicians in providing quality care and avoiding medical errors. Not only is this the ethical thing to do for patients, but these actions will result in cost savings for Medicare and other programs. In addition, physicians continue to be exposed to escalating practice costs, declining Medicare payments, and increasing professional liability premiums. It will become increasingly difficult to fund health care information technology investments in the current cost and reimbursement environment. Finally, it is unfair to ask the physician community to carry a disproportionate financial burden for an investment that benefits the entire health care system. *Therefore, we ask that CMS continue to explore mechanisms to ensure that physicians and patients have access to health care information technology.*

I. AAOS Expresses Concern Regarding Defining and Calculating the Value of the Protected Technology

[Electronic Prescribing Exception: § 411.357(v); 3. Additional Limitations on the Provision of Electronic Prescribing Technology; (b) Value of Protected Technology & Pre-Interoperability Exception: §411.357(w); (e) Value of Protected Technology & Post-Interoperability Electronic Health Records Exception: §411.357(x); (e) Value of Protected Technology]

Given possible fraud and abuse concerns, AAOS appreciates CMS' questions regarding a possible limit on the value of the items and services ("covered technology") that could be provided to a physician by a single donor. However, we are concerned that the regulation could become an additional impediment to the proliferation of beneficial technology depending on how the value caps are defined and calculated. In defining and calculating the value of the donation, we believe that the process must be rational and transparent. In addition, the process must not act as an impediment to those organizations that wish to donate the covered technologies to physicians for quality, efficiency, and safety reasons.

Therefore, we ask that CMS base any limits on the value of covered technology on actual dollar amounts and that those actual dollar amounts be calculated via the amount spent by the donor. If the value were not calculated under this methodology, two major concerns would arise. First, the administrative costs and lack of transparency associated with estimating the "value to the recipient" would severely outweigh the minimal concerns about fraud and abuse. The few fraud and abuse concerns in this area will be

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addressed by simply having a cap. Second, any benefits to the health system that would be accrued by large purchasers who receive cost discounts on the technology would be diluted. Some large purchasers will be able to obtain better prices, and therefore, may be able to donate some of the better and newer technology. While we understand CMS' reasoning that donors should only be offering technology that is necessary for improving the quality and efficiency of care, as well as that it be tailored to the technologies that CMS is attempting to address in this proposed rule, it is in the interest of the patient and the health care system for that covered technology to be as up-to-date and functional as possible. The ability to access those technologies could be enhanced by ensuring that the value is calculated in a way that does not constrict donors and recipients without regard for the prices that the donors are able to procure.

In addition, CMS stated its concern that the cap might place a disadvantage on smaller entities that do not have the financial resources of larger organizations. This concern is avoided if the value is calculated by the actual amount spent by the donor as long as the cap is set and updated at an amount that reflects a fair market price. Setting the dollar amount without regard for technology changes, inflation, or other market factors interferes with the market and the ability to access those resources. *Therefore, we also ask CMS to create an iterative process for calculating the cap that takes into account the decreasing costs of "next generation" technologies as well as the increasing costs associated with new and updated technologies.*

II. AAOS Supports the Inclusion of Non-drug Prescription Functionality of Covered Technology.

[Electronic Prescribing Exception: §411.357(v); (3) Exceptions Additional Limitations on the Provision of Electronic Prescribing Technology; (a) Promoting Compatibility and Interoperability & Pre-Interoperability Electronic Health Records Exception: §411.357(w);(a) Covered Technology]

In both the electronic prescribing exception and the pre-interoperability electronic health records exception, CMS solicited comments on whether to permit the covered prescribing technology (and electronic health records with prescribing technology) to include prescribing functionality "for items and services that are not drugs."

One of the clear goals of fostering the adoption of electronic prescribing technology is to reduce prescription drug medical errors. While AAOS understands that the proposed rule is written narrowly, reducing prescription drug errors is not the only goal of the exceptions. In addition to medical error reduction, the covered technologies deserve

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protection because of the benefits that accrue to patients, the long-term cost control benefits that accrue to payers, and the increased efficiency with which physicians provide care. In addition to prescribing medication, orthopaedic surgeons also write prescriptions for durable medical equipment (DME), laboratory tests, biologics, devices, and rehabilitation. While we believe most, if not all, orthopaedic surgeons will find utility in the covered technologies that only include drug functionality, from an efficiency and interoperability stand-point, it is not rational to exclude non-drug prescription orders.

Therefore, AAOS recommends that CMS allow the covered technologies to be used for the transmission of prescription information regarding items and services that are not drugs. Inclusion of that functionality carries with it no additional risk of fraud or abuse, and it encourages the utilization of integrated systems that will improve patient care. The exception's "used solely" requirement is already written in such a way that it runs the risk of being unduly narrow. By allowing the prescription functionality to include non-drug items and services, it enhances the value of this rule in fostering technology adoption.

III. Conclusion

AAOS appreciates CMS' efforts and the opportunity to participate in the rulemaking process. While there are other areas of concern in the proposed rule, including the burden that the rule places on physicians in certifying that donated items or services are not functionally equivalent to items or services already possessed, AAOS appreciates CMS' attention to the issues of calculating the value of the covered technology and the non-drug functionality of the prescribing component.

If there is any other information or assistance that AAOS can provide, please do not hesitate to contact us.

Sincerely,

Stuart L. Weinstein, M.D.
President

CMS-1303-P-23 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Mrs. Sue Ehinger **Date & Time:** 12/12/2005

Organization : Parkview Health

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

? The safe harbors do not go far enough and will not stimulate the desired change (increased use of technology) while balancing the risk (buying patients via soft kick backs).
? The focus is on start-up costs (hardware, software, training) and not total cost of ownership (TCO), which is not realistic especially for the smaller physician office. Any cap that is considered should be on TCO, and the allowed donations should include the post-implementation services.
? The focus on EMR and e-prescribing is too narrow and should be expanded to include turn key support for other technology enabled care (telemedicine, clinical decision support).
? Maintenance of the requirement that the tools were used solely for the purpose of transmitting and receiving EMR/prescription drug information would be virtually impossible.
? Without standards and product certification criteria, interoperability will be difficult to achieve and organizations will spend considerable resources to achieve the desired outcome.
? The government should consider extending the RHIO safe harbors to this context if the receiver of the donation shows intent to share information gathered for the purpose of public health, outcome studies, and improved patient care.

? Consider special tax incentives for the donating entity.

CMS-1303-P-24 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : **Date & Time:** **12/12/2005**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

CMS-1303-P-25 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Jacquline Studer **Date & Time:** 12/12/2005

Organization : GE Healthcare Information Technologies

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment - GE Response to HHS Proposed Regulations Providing Stark Law Exceptions and Anti-kickback Law Safe Harbors for Electronic Prescribing and Electronic Health Records

CMS-1303-P-25-Attach-1.DOC

540 West Northwest Highway
Barrington, IL 60010
USA

December 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:

GE is pleased to submit our comments regarding the Centers for Medicare & Medicaid Services (CMS) Proposed Rule on providing Stark Law exceptions 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 protections for donations of eRx and EHRs. The proposed exceptions along with the proposed Anti-kickback Law 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.

GE believes that exceptions 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.

GE 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, GE 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 GE 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 Law exceptions can be structured to incentivize the market to drive rapid interoperability. GE 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.

Interoperability furthers the underlying purpose of both the Stark Law and the Anti-kickback Law. As discussed in the preamble to both Phase I and Phase II of the Stark Law regulations, the impetus behind the statute was numerous studies showing that utilization of certain services increased if the physician had a financial relationship to the service provider. See 69 Fed. Reg. 16,054, 16,056 (Mar. 26, 2004), 66 Fed. Reg. 856, 859-60 (Jan. 4, 2001). The Stark Law was intended to sever this link and help remove financial considerations from physician decision-making. Similarly, in issuing the initial Anti-kickback Law regulatory safe harbors, the OIG expressed concern that certain business relationships might affect a physician's exercise of "sound, objective medical judgment." See 54 Fed. Reg. 3,088, 3,089 (Jan. 23, 1989). In a subsequent issuance, the OIG noted that, among other risks, "kickback schemes can freeze competing suppliers from the system." See 56 Fed. Reg. 35,952, 35,954 (July 29, 1991). By diminishing the possibility of donors locking recipients into their network, including effective interoperability policies in the proposed exceptions and safe harbors will further the underlying goals of both of these statutes.

* * *

We look forward to working with the Department and our healthcare industry colleagues to make responsible changes to the Stark Law exceptions that will advance HIT implementation in support of improved patient safety and healthcare quality. If you have any additional questions please contact Hugh Zettel, at hubert.zettel@med.ge.com (262)-293-7493.

Sincerely,

Jacqueline Lee Studer
Associate General Counsel
GE Healthcare

GE Response to HHS Proposed Regulations Providing Stark Law Exceptions and Anti-kickback Law Safe Harbors for Electronic Prescribing and Electronic Health Records

***December* 12, 2005**

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

GE is pleased to submit our comments regarding the Centers for Medicare and Medicaid Services CMS-1303-P and Office of the Inspector General (OIG) OIG-405-P Proposed Rules on the Stark Law exceptions and Anti-kickback Law safe harbors respectively for electronic prescription services (eRx) and Electronic Health Records (EHRs). The proposed Stark Law exceptions 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.

GE believes that exceptions and 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 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. 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 the patient.

GE 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, GE believes that the interoperability policy component 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.

GE 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 GE believes that interoperability requirements must be driven by predicating the receipt of government financial and regulatory incentives on conditions that demand interoperability in practice.

Interoperability furthers the underlying purpose of both the Stark Law and the Anti-kickback Law. As discussed in the preamble to both Phase I and Phase II of the Stark Law regulations, the impetus behind the statute was numerous studies showing that utilization of certain services increased if the physician had a financial relationship to the service provider. See 69 Fed. Reg. 16,054, 16,056 (Mar. 26, 2004), 66 Fed. Reg. 856, 859-60 (Jan. 4, 2001). The Stark Law was intended to sever this link and help remove financial considerations from physician decision-making. Similarly, in issuing the initial Anti-kickback Law regulatory safe harbors, the OIG expressed concern that certain business relationships might affect a physician's exercise of "sound, objective medical judgment." See 54 Fed. Reg. 3,088, 3,089 (Jan. 23, 1989). In a subsequent issuance, the OIG noted that, among other risks, "kickback schemes can freeze competing suppliers from the system." See 56 Fed. Reg. 35,952, 35,954 (July 29, 1991). By diminishing the possibility of donors locking recipients into their network, including effective interoperability policies in the proposed exceptions and safe harbors will further the underlying goals of both of these statutes.

A summary of GE's key recommendations regarding the proposed exceptions and safe harbors for eRx and EHRs is given below, with detailed explanations in the appropriate comment sections that follow this summary.

A. GE 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. GE 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 an EHRs must not explicitly or implicitly be only the EHR/clinical component or the 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 a more robust EHRs (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. GE 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 interoperability requirements (as required by CCHIT or HITSP).
   - 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 interoperability standards.

C. GE supports several measures to help ensure that this regulatory relief incentivize interoperability in actual care settings and robust competition
   - Donating proprietary solutions locks 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. Interoperability is a cost and will not be incurred unless it is mandated or if there is a corresponding benefit. GE believes that market incentives work much better than government mandates to drive beneficial behavior. Therefore, GE 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 regulatory relief is conditioned upon donors being required to donate and use EHRs from multiple vendor. Regulatory relief must 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 implement the following requirements:

- 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. The value of the cap should be based on the projected level of savings to be achieved from the implementation of EHRs and eRX based on the size of the physician practice. The cap amount would be framed as a "not to exceed" contribution level towards the purchase of any eRx or EHR software similar to a coupon.
- 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 EHRs, submitted to all applicable certified EHRs as listed by CCHIT.
- Practices that have already implemented EHR functionality equivalent to that offered by the donating entity that meets or can demonstrate an upgrade path to HHS-mandated interoperability requirements should be compensated on a pro rata basis for the applications that the practices have already put in place.
- GE supports a provision that requires donating entities to provide data-migration services if a physician chooses to leave and purchase their own EHRs, eliminating the most restrictive lock-in restriction. Note that this requirement becomes less of an issue as vendors implement standards-based interoperability solutions.

D. GE supports interoperability requirements that place emphasis on interoperability policies than ensures 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 EHRs set forth by HHS.
- The patient information provided to donated EHRs must provide the same level of information interoperability (as defined by CITL's four levels of interoperability, Walker, Pan, et al, Health Affairs, January 19, 2005, pg. W5-11) as EHRs used by the donating entities physicians.

E. GE 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. GE believes that greater regulatory relief should be afforded to HIEs using heterogeneous vendors systems as such HIEs are the best mechanism for achieving interoperability as has been demonstrated in

over ____ such HIEs operating today. GE notes that Senate Bill S1418 includes language regarding grant requirements recognizing the value of community-wide HIEs in its grant qualification criteria.

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)

GE 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 exceptions and safe harbors, but do include it in the eRx exception and 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 EHRs must include eRx to qualify for protection under an exception or 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. GE suggests that connectivity and installation assistance should be a defined benefit of the agreement under the exceptions and safe harbors, 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, GE 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)

GE 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 (EHRs) as providers may wait to adopt technology until a donation is provided, GE 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.

GE 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 Law exceptions and Anti-kickback Law safe harbors for electronic prescription services (eRx) and Electronic Health Records (EHRs).

3. CMS and OIG ask respondents to comment on the proposed exceptions and safe harbors 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, GE 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, GE recommends that the exceptions and safe harbors be extended to cover these elements, provided that these elements are combined in a single transaction with the donation of the other exception or safe harbor elements of eRx and EHRs and where equivalent functionality does not already exist.

GE 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 exception or 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)

GE interprets that standards used in this context relates 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. GE 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 EHRs. 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. The Department should investigate calculating an overall donation cap that approximates the total savings to be achieved over a specified period of time and practice size (See our response in number 17). 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)

GE 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. Donor's costs for donating EHRs and eRX are ultimately passed through to federal healthcare programs and other recipients if such costs do not ultimately result in savings for healthcare delivery. Most of the cost savings projected to be realized through the adoption of healthcare IT are only realized if EHRs are interoperable and if there is robust competition. The permitted donation must approximate the projected cost savings. Otherwise the donations could result in increased costs that amount to federal government subsidies to lock in incumbent vendor systems and provider referral networks. GE appreciates the concern regarding donors shifting the cost of EHRs 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 EHRs. 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 approximates the total savings to be achieved over a specified period of time and practice size. In addition, regulatory relief must be conditioned upon the achievement of interoperability and ensuring that there is robust competition in the EHR market. This builds in cost shifting protection since overall costs will be reduced through robust competition and the Department can recognize "minimum" benefits to be realized in the outgoing years as cost savings are achieved. The Department should incentivize the donating entity and recipient to achieve those cost savings benefits. In addition, financial risk beyond the implementation phase should be mitigated as pay for performance incentives are implemented.

GE 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 an exception or 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)

GE encourages the Department to consider extending exception and safe harbor protection 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.

GE 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 Law exceptions and Anti-kickback Law safe harbors for electronic prescription services (eRx) and Electronic Health Records (EHRs). .

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)

GE 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, GE 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 the Stark Law exceptions and Anti-kickback Law safe harbors could incent physician participation due to the neutral governance and the interoperability enforcement provided by the HIEs. Given that physicians typically have privileges at multiple hospitals, HIEs provides a natural infrastructure for cost effectively 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 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 anti-kickback statute protection with the existing Stark exemption for Community Wide Health Information Systems would provide 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 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 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.

8. CMS and OIG ask respondents to comment on whether the exceptions or safe harbors 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. GE 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 an 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.

GE 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.

GE believes that the interoperability policy component must be used to drive the market to demand the technology component of interoperability for eRx and EHRs. 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. GE 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 technologies in general, the pre and post interoperability phases for EHRs 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. GE emphasizes that EHR certification does not address interoperability policies that donating entities must follow to ensure that interoperability capabilities of the certified EHRs are deployed, and there are countless examples today where entities utilize open, non-proprietary standards, but administer information exchange via proprietary policies.

GE 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." The amount of fragmentation in our marketplace today is due to hospitals and other entities that view patient information as proprietary, controlling access to these information silos as a means of locking in physicians and patients. The entities selection and implementation of donated EHRs would provide a new tool to lock in recipient physicians and their patients, resulting in limiting their access to competitive services and new services such as Patient Health Records. To suggest the contrary would not explain the reluctance of hospitals and other entities from participating in health information exchanges. In the context of comparing these entities with ancillary services such as laboratories relative to embracing interoperability to achieve portability of patient information wherever and whenever the providers that are delivering care need it, all are equally guilty.

GE 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 EHRs 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 EHRs 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 EHRs used by the donating entities physicians.
4. The exceptions and safe harbors 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 at a rate equal to the value of the donation to eligible entities that do not have equivalent technology.
6. Donating entities should be required to provide data-migration services if a recipient later chooses to purchase his/her own EHRs. This eliminates the greatest potential lock-in restriction for the donating entity. This finanical requirement to the donor is reasonable because it becomes less of an issue as vendors implement standards-based interoperability technology.
7. 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 EHRs, submitted to all applicable certified EHRs as listed by CCHIT.

GE 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." GE 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, EHRs or eRx systems 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, GE 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 already exchanging medical summaries and medication lists TODAY!

GE 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 EHRs 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 GE 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 EHRs 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)

GE 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 EHRs. EHRs should be viewed to include not only 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 healthcare 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. Donor's costs for donating EHRs and eRX are ultimately passed through to federal healthcare programs and other recipients if such costs do not ultimately result in savings for healthcare delivery. Most of the cost savings projected to be realized through the adoption of healthcare IT are realized only if EHRs is interoperable and if

there is robust competition. The amount of the cap must approximate the projected cost savings. Otherwise the donations could result in increased costs that amount to federal government subsidies to lock in incumbent vendor systems and provider referral networks. The Department should investigate calculating an overall donation cap that approximates the total savings to be achieved over a specified period of time and practice size. In addition, regulatory relief must be conditioned upon the achievement of interoperability and ensuring that there is robust competition in the EHR market. This builds in cost shifting protection since overall costs will be reduced through robust competition and the Department can recognize "minimum" benefits to be realized in the outgoing years as cost savings are achieved. The Department should incentivize the donating entity and recipient to achieve those cost savings benefits. In addition, financial risk beyond the implementation phase should be mitigated as pay for performance incentives are implemented.

The cap for the donated EHR software should be treated as a not-to-exceed value (like a coupon), where the donor can recognize a base amount for a recognized fair market value, and the recipient can choose to purchase competing equivalent software with the coupon provided by the donor.

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

There is a potential opportunity to incent standards adoption by increasing donation caps commensurate with the increased savings that may be achieved using cost saving, value producing market structures, such as the utilization of the EHRs within an HIEs.
GE 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.

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

GE 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.

12. CMS and OIG ask respondents to comment on whether the exceptions and safe harbors 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)

GE 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 EHRs 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 EHRs; this standards process could become a barrier to adoption. eRx 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 Kingdoms definition in which most doctor ordering is called 'prescribing) should be the focus. eRx (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/EHRs 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 exceptions and safe harbors should address the issue of whether recipients of donated EHRs would intentionally divest themselves of functionally or technically equivalent technology that they already possess to shift costs to Donors. (Pg. 59018, col. 1pg. 59023, col. 1) (Pre-Interoperability Electronic Health Records Exception: Electronic 411.357w)

GE 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 (EHRs) as providers may wait to adopt technology until a donation is provided, GE 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.

Understanding the Department's interest in achieving widespread adoption of the EHRs throughout the U.S and interest in the success of the American Health Information Community (AHIC) and the associated contracts, GE 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 EHRs 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 EHRs are compliant with Public Health Information Network and BioSense preparedness standards. (Pg. 59022, col.2) (Pre-Interoperability Electronic Health Records Exception: Electronic 411.357w)

GE is actively supportive of the work being accomplished by the federal government to develop the Public Health Information Network (PHIN). However, an interoperable framework and interoperable EHRs are essential for an effective PHIN. GE cautions the Department that it is in the best position to develop a process that provides market incentives for driving interoperability. GE 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, GE believes that the interoperability policy component 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.

GE 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 GE believes that interoperability requirements must be driven by predicating the receipt of government financial and regulatory incentives on conditions that demand interoperability in practice.

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

Finally, GE 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 EHRs 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)

GE encourages the Department to grant EHRs 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:

GE appreciates the opportunity to comment on the issue of necessary non-monetary remuneration. We are concerned that the distinctions drawn between software and hardware effectively do not include hardware from the EHR exceptions and safe harbors, but includes it in the eRx exception and 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 EHRs must include eRx to qualify for protection under an exception or safe harbor.

For further clarification, GE 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. GE 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 EHRs 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 EHRs (patient demographic, eligibility

and claims data). Data from billing and scheduling systems is the 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 under the exceptions and safe harbors, 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)

Donor's costs for donating EHRs and eRX are ultimately passed through to federal healthcare programs and other recipients if such costs do not ultimately result in savings for healthcare delivery. Most of the cost savings projected to be realized through the adoption of healthcare IT are realized only if EHRs is interoperable and if there is robust competition. The amount of the cap must approximate the projected cost savings. Otherwise the donations could result in increased costs that amount to federal government subsidies to lock in incumbent vendor systems and provider referral networks. The Department should investigate calculating an overall donation cap that approximates the total savings to be achieved over a specified period of time and practice size. In addition, regulatory relief must be conditioned upon the achievement of interoperability and ensuring that there is robust competition in the EHR market. This builds in cost shifting protection since overall costs will be reduced through robust competition and the Department can recognize "minimum" benefits to be realized in the outgoing years as cost savings are achieved. The Department should incentivize the donating entity and recipient to achieve those cost savings benefits. In addition, financial risk beyond the implementation phase should be mitigated as pay for performance incentives are implemented.

In addition, GE supports the NPRM requirement that donated software/systems cannot be used to replace existing capabilities already in place at the physician practice. However, to avoid a "chilling" effect on the deployment of both eRx and EHRs as providers may wait to adopt technology until a donation is provided, GE 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.
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.
GE also refers OIG to the responses regarding caps in Questions #5, #10, #17 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)

Donor's costs for donating EHRs and eRX are ultimately passed through to federal healthcare programs and other recipients if such costs do not ultimately result in savings for healthcare delivery. Most of the cost savings that are projected to be realized through the adoption of healthcare IT are only realized if EHRs is interoperable and if there is robust competition. In addition, the cost savings must approximate the amount of the donation. Otherwise the donations could result in increased costs that result in federal government subsidies to lock in incumbent vendor systems and provider referral networks. GE appreciates the concern regarding donors shifting the cost of EHRs 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 EHRs. 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 approximates the total savings to be achieved over a specified period of time and practice size. In addition, regulatory relief must be conditioned upon the achievement of interoperability and ensuring that there is robust competition in the EHR market. This builds in cost shifting protection since the Department can recognize "minimum" benefits to be realized in the outgoing years, and it should incentivize 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)

GE 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." The amount of fragmentation in our marketplace today is due to hospitals and other entities that view patient information as proprietary, controlling access to these information silos as a means of locking in physicians and patients. The entities selection and implementation of donated EHRs would provide a new tool to lock in recipient physicians and their patients, resulting in limiting their access to competitive services and new services such as Patient Health Records. To suggest the contrary would not explain the reluctance of hospitals and other entities from participating in health information exchanges. In the context of comparing these entities with ancillary services such as laboratories relative to embracing interoperability to achieve portability of patient information wherever and whenever the providers that are delivering care need it, all are equally guilty.

As for the list of donors, GE 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) 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 the Stark Law exceptions and Anti-kickback Law safe harbors could incent physician participation due to the neutral governance and interoperability enforcement provided by the HIEs. Given that 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, out 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 anti-kickback statute protection with the existing Stark exemption for Community Wide Health Information Systems would provide 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 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.

19. CMS and OIG ask respondents to comment on whether the exceptions and safe harbors should protect additional software applications, provided eRx, and EHRs 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)

GE 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. GE 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 an EHRs 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 a more robust EHRs (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.

GE suggests that the scope of solutions within the exceptions and 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 EHRs (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 exceptions and safe harbors should include other categories of donors and recipients. (Pg. 59023, col. 1,3) (Pre-Interoperability Electronic Health Records Exception: Electronic 411.357w)

GE 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 of "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, GE 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 the Stark Law exceptions and Anti-kickback Law safe harbors could incent physician participation due to the neutral governance and interoperability enforcement provided by the HIEs. Given that physicians typically have privileges at multiple hospitals, HIEs provides a natural infrastructure for cost effectively interconnecting multiple competing entities with recipients. HIEs could also provide 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, out of the 109 HIEs qualified in the survey, there are already 25 HIEs that are fully operational, with another 40 in

the implementation phase. OIG should review the governance models of these HIEs for recommended regulations that mitigate the risk of fraud and abuse. Coupling HIE anti-kickback statute protection with the existing Stark exemption for Community Wide Health Information Systems would provide 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 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.

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)

GE 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. GE is also concerned about providing equitable access to safety net providers or rural market providers as recipients of donated EHRs and suggests including equal access language to ensure that these entities could participate as recipients of donate eRx or EHRs.

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

Donor's costs for donating EHRs and eRX are ultimately passed through to federal healthcare programs and other recipients if such costs do not ultimately result in savings for healthcare delivery. Most of the cost savings projected to be realized through the adoption of healthcare IT are realized only if EHRs is interoperable and if there is robust competition. The amount of the cap must approximate the projected cost savings. Otherwise the donations could result in increased costs that amount to federal government subsidies to lock in incumbent vendor systems and provider referral networks. The Department should investigate calculating an overall donation cap that approximates the total savings to be achieved over a specified period of time and practice size. In addition, regulatory relief must be conditioned upon the achievement of interoperability and ensuring that there is robust competition in the EHR market. This builds in cost shifting protection since overall costs will be reduced through robust competition and the Department can recognize "minimum" benefits to be realized in the outgoing years as cost savings are achieved. The Department should incentivize the donating entity and recipient to

achieve those cost savings benefits. In addition, financial risk beyond the implementation phase should be mitigated as pay for performance incentives are implemented.

In addition, GE supports the NPRM requirement that donated software/systems cannot be used to replace existing capabilities already in place at the physician practice. However, to avoid a "chilling" effect on the deployment of both eRx and EHRs as providers may wait to adopt technology until a donation is provided, GE 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. 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.

GE 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.

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)

GE 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 EHRs. Data regarding successful EHRs implementations points to physician readiness and acceptance to make the necessary workflow and operational business changes required when implementing EHRs as critical to success. 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 EHRs adoption as physician expectations of "free" software freezes the current market momentum. Second, it puts focus on EHRs adoption without the commensurate interoperability policies that ensure portability of health information, resulting in proprietary solutions that locks in incumbent vendors and provider referral networks, and increasing barriers to a transparent efficient healthcare market.

GE suggests that both EHRs 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 anti-kickback statute changes that support participation in HIEs.

GE 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 the Anti-kickback Law safe harbors 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, out 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 additional 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. GE recommends that OIG review the governance models of these HIEs for recommended regulations that mitigate the risk of fraud and abuse. Coupling HIE anti-kickback statute protection with the existing Stark exemption for Community Wide Health Information Systems would provide 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.