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December 12, 2005

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
Hubert Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Comments on Proposed Rule to Create an Exception to the Physician Self-Referral Prohibition in Section 1877 of the Social Security Act for Certain Electronic Prescribing Arrangements (CMS-1303-P) (published at 70 Federal Register 59182, October 11, 2005)

Dear Dr. McClellan:

Caremark appreciates the opportunity to provide comments on the proposed rule to establish a new exception to the physician self-referral prohibition in section 1877 of the Social Security Act for certain arrangements involving the provision of electronic prescribing ("e-prescribing") technology to physicians. We strongly support Congress' and the President's goal of achieving widespread adoption of interoperable electronic health records for the purpose of improving the quality and efficiency of health care, while maintaining the levels of security and privacy that consumers expect.

Caremark Rx, Inc. ("Caremark") is a leading pharmacy benefit management ("PBM") company, providing through its affiliates comprehensive drug benefit services to over 2,000 health plan sponsors and their plan participants throughout the U.S. Caremark's clients include employers, health plans, managed care organizations, insurance companies, unions, government agencies, including the Federal Employees Health Benefits Program ("FEHBP"), CalPERS, and other funded benefit plans. Caremark develops and administers formularies for many of these clients through its independent P&T Committee. Caremark operates a national retail pharmacy network with over 55,000 participating pharmacies, seven mail-service pharmacies, the industry's only FDA-regulated repackaging plant, and 21 specialty pharmacies for the delivery of advanced medications to individuals with chronic or genetic diseases and disorders. Caremark processes over 550 million prescriptions annually.

E-prescribing is a critical component of that envisioned electronic health care system, and both Congress and the Administration have recognized its value as a "vehicle to reduce medical errors and to improve efficiencies" in the health care system. E-prescribing

reduces medication errors and improves efficiency by eliminating illegible handwriting, and allowing plans to send physicians important messages, such information about other medications their patients may be taking to prevent adverse drug events and to inform them of more cost effective generic alternatives. It is through this prescribing decision-support messaging that e-prescribing technology can achieve its full potential as a mechanism for improving medication safety and compliance, and thereby delivering not only cost savings, but better quality of care.

We commend the Centers for Medicare and Medicaid Services ("CMS") for seeking to encourage the adoption of electronic health records and supporting technology, including e- prescribing technology, for Medicare Part D. Since the benefits of e-prescribing extend beyond Part D to all parties that participate in the health care system, including the government, private sector, health care providers, health care organizations and patients, it is in the interests of all these parties that the safe harbor be interpreted as broadly and flexibly as possible, so that these benefits may soon be realized.

General Comments

Throughout the preamble to the proposed rule, CMS emphasizes its concern to safeguard against "abusive arrangements in which the remunerative technology might constitute a payment for referrals." [1]

However, noticeably absent from the preamble is reasoning to suggest why the provision of e-prescribing technology to physicians is likely to induce referrals or increase prescribing. Perhaps more importantly, the preamble demonstrates the lack of consideration of whether donors such as Part D sponsors or MA organizations, which are at-risk entities, would in fact be adversely impacted by increased utilization. Thus, far from seeking to encourage over-utilization, they have every incentive to do just the opposite. Finally, potential donors do not have limitless resources that they are willing to bestow indiscriminately on physicians without consideration as to whether those physicians need the technology, would benefit from the technology, or are likely to use it. Donors have limited resources and will therefore, likely take great care to target existing high-volume paper physicians, where the impact of the technology and its benefits, both in terms of quality of care and cost savings, will be the greatest. While the cost of providing e-prescribing technology to a single physician is relatively modest (and so unlikely to exert an undue influence on that physician's decision-making), it must be provided to a substantial number of physicians before its impact can truly be felt on a patient population. The aggregate costs can quickly approach hundreds of thousands of dollars or more. Therefore, donors will not want to provide it to physicians who already have e-prescribing technology, or to those physicians who engage in little or no

[1] 70 Fed. Reg. (October 11, 2005) at 59185.

prescribing, and they will be most unwilling to expend those resources on e-prescribing technology that is so circumscribed in its applications, and of such limited utility, that physicians are unlikely to use it.

For all these reasons, there appears to be somewhat of a disconnect between the perceived risks that the proposed rule seeks to protect against and the reality of the e-prescribing environment. As a result, many of the restrictions and limitations in the proposed rule appear to be unnecessary, and some even counterproductive. While we understand the desire to prevent any party from obtaining an undeserved benefit, whether legal or illegal, from the e-prescribing technology, we are concerned that CMS has drifted from what should be its true focus, namely, preventing abusive self-referral situations and, as a result, has imposed more restrictions and conditions than are necessary or appropriate. These restrictions will make it difficult for the e-prescribing technology to deliver on its promise of reduced medication errors, improved clinical outcomes and greater efficiency. Rather than effectuate Congress' intent, the narrow prism through which the new exception has been interpreted will serve only to frustrate it.

Therefore we urge CMS to reconsider its approach to the exception in several respects. First, the focus and orientation should be on finding legitimate avenues to facilitate the spread of e-prescribing technology and activity, rather than seeking ways to limit these. Rather than viewing the exception as a mechanism to impose "stricter conditions," it should instead be viewed as a means to expand and promote such activities. In this regard, the interests of donors and the Administration are very much aligned, in that both share the goal of moving the health care industry towards a system of electronic health records through the widespread adoption of e-prescribing and other electronic health transactions and activities. Second, a distinction should be made between those donors in a position to receive and benefit from referrals, versus those donors that are not in such a position, and/or whose economic incentives are to reduce, rather increase, referrals and utilization. While the exception should apply to all the specified permitted donors, it is reasonable to impose some financial and other parameters around donations by entities that potentially stand to benefit from referrals, since they do not experience the same economic constraints that apply to other donors. In contrast, for those donors that do not benefit economically from, and are actually adversely impacted by, increased utilization, there is little need to impose restrictions. Not only do they lack the economic incentive to abuse the exception, but their own economic constraints will naturally limit their donations and cause them to appropriately target these to achieve the greatest conversion from paper to electronic prescribing.

Specific Comments

A. Exception for Certain Arrangements Involving Electronic Prescribing Technology: §411.357(v)

1. Protected Non-Monetary Remuneration

(a) "Necessary" Non-Monetary. CMS points out that the proposed exception would protect only items or services "necessary" to conduct e-prescribing transactions. In order to ensure this, CMS proposes to require recipients to certify that the items or services provided are not technically or functionally equivalent to items or services the recipients already possess. CMS requests comments to address the risk that recipients may divest themselves of functionally or technically equivalent technology that they already possess in order to shift costs to donors.

We believe that CMS's concern here is misplaced. First, we believe it involves an overly restrictive interpretation of the word "necessary" in the Medicare Modernization Act ("MMA"). Congress' intent with this word was simply to ensure that, as an objective matter unrelated to the particular recipients, the technology provided to physicians is required in order to do e-prescribing. So, for example, it would not be appropriate to allow the lease of offices in which the e-prescribing occurs to fall under the safe harbor, since offices are not necessary or required in order to effect an e-prescribing transaction. It has nothing to do with the circumstances of the particular recipient, or whether the recipient has existing e-prescribing technology.

Second, even if the recipient did have e-prescribing technology, this would be a business concern for the donor to address, as would the possibility of the recipient shifting costs to the donor, and not an instance of illegal conduct that CMS should seek to prohibit. Since the donor will be expending its funds to promote e-prescribing, it has every incentive to take steps to ensure that its technology is given to those it believes will benefit the most from it, and to prevent physicians from taking advantage of the situation by shifting costs to it. Since there is no reason to believe that, even if it did occur, "shifting costs" are linked to increased or induced referrals in some way, it should be outside the purview of CMS.

Finally, the "technically or functionally equivalent" test is vague (and so likely to become a source of uncertainty and increased risk) and overly broad. As such, it would disallow the donation of much technology that would significantly improve the e-prescribing experience, and thereby promote its greater use, even though it may be "technically and functionally equivalent" to technology that the physician already has. For example,

technology with greater capacity, memory, speed, mobility, among other things, may ultimately work the same way to perform the same functions, but simply do it better, faster or more conveniently. As technology continues to develop and change, trying to invest these terms with a fixed meaning will be futile, which is all the more reason to allow the market, business and economic interests of the donor to determine what technology it should donate to achieve the donor's legitimate goal of encouraging e-prescribing rather than paper prescriptions.

Recommendation: Since the appropriate use of the donated technology for the intended purpose is primarily a donor concern rather than a self-referral risk, donors should be allowed to choose whether to seek any certification by the physician concerning his/her existing technology. It should similarly be the donor's decision as to how it will protect against the inappropriate shifting of costs to it by physicians. The "technically and functionally equivalent" standard is in any event flawed, since it would potentially disallow technology that will significantly improve the e-prescribing experience, and so appropriately promote its use.

(b) "Used Solely". CMS proposes to use its regulatory authority under section 1877B(b)(4) to create an additional exception to protect the provision of technology that is used for more than one function, so long as a substantial use of the items and services is to receive and transmit e-prescribing information. CMS seeks comments on methodologies to quantify or otherwise ensure this "substantial" use for e-prescribing and on the nature and amount of any cap it might impose on the value of donated multi-functional hardware or connectivity services.

We commend CMS for its recognition that most users prefer a single, multi-functional device, rather than many single-use devices. Indeed, it is becoming increasingly rare to find single-use devices, and so CMS's decision to use its regulatory authority to allow the provision of multi-functional technology will be a critical facilitating requirement in order for the exception to be meaningful.

We are concerned, however, that CMS believes it necessary to qualify this by requiring that a "substantial" use be for e-prescribing, and that this substantial use be quantifiable or otherwise measurable. We do not believe this is necessary or practical. All that should be required is that one function of the technology, perhaps even a main function of the technology, be for e-prescribing. This would include not only the transmission and receipt of the actual prescription itself, but also the transmission of medication history, formulary information and potentially other prescription-related information, if and when final standards for these transactions are adopted. That the device potentially could be, or indeed is, used for other purposes does not diminish its value for e-prescribing or mean

that it is more likely to induce referrals, especially to those donors that have no incentive to increase referrals and in fact work to reduce utilization. Indeed, hand-held devices increasingly are being designed and marketed as a bundle to the operating system, with calendar, address list and other functionalities and services.

Not only would it be very costly to purchase and support devices that are custom-built solely for e-prescribing, but it would be counterproductive, since physicians expect and demand multi-functional devices that allow them to perform many different tasks. Indeed, this limitation could actually deter physicians from using the e-prescribing device if they have to use another, similar device for other purposes. If donors are limited to donating sub-optimal technology that physicians do not want to use, they will simply not use it, thereby defeating the purpose of the exception. As long as the technology is provided for e-prescribing purposes and one of its functions and uses is for e-prescribing, it meets the objective and requirements of the exception, and should be allowed. In the case of hospital and group practice donors, where the donor could potentially benefit from the referral of other services, the additional safeguard could be added that the device should not include custom software and functionalities that are not part of the standard bundled software for this type of device.

In addition, we do not believe there is a need to cap the value of multi-functional technology, any more than there is a need to cap the value of other donated e-prescribing technology. As mentioned previously, donors do not have unlimited resources, and most already have set budgets and internal financial constraints on what they may spend to promote e-prescribing. As such, it is in their own economic interests to ensure that the technology they provide is the most likely to achieve the intended purpose of promoting e-prescribing, and their own financial constraints that will naturally limit the amount they spend for this purpose. Imposing a cap, even if not a fixed dollar cap, will unnecessarily limit the utility of the exception, since many physicians see little personal economic benefit from engaging in e-prescribing, and so will not invest in it. As such, arbitrarily capping donated technology to a fixed dollar amount or even to percentage of the total technology will in many instances result in donors being forced to provide sub-optimal technology, less useful technology or partial or outdated technology, with the result that physicians will be less likely to use it.

Finally, we urge CMS to adopt a broader definition of the term "multi-functional items or services" that will be eligible for the new exception. CMS proposes to allow "hardware (including necessary operating system software) and connectivity services that are used for more than one function" to be covered. As mentioned above, software that is not required to operate the hardware, but that is commonly bundled with it to make for a more useful device, such as calendar, contacts and word processing software, should be covered. In addition, this exception, as with the general exception, should also cover

information technology support services such as installation, implementation, training and maintenance services. These support services are an integral part of the e-prescribing technology, an important factor in removing barriers to adoption of e-prescribing, and essential to ensure its proper and smooth functioning. Without these support services, even the most advanced hardware and software will be of little practical value.

Recommendation: CMS should use its regulatory authority under section 1877B(b)(4) to provide an exception for multi-functional technology, provided that one of the functions of that technology is to receive and transmit e-prescribing transactions. This exception is critical in order that the intent of Congress in enacting section 1860D-4(e)(6) of the MMA can be given practical effect. CMS should not require that a "substantial" use of the technology be for e-prescribing, or to impose a cap on the amount of multi-functional technology donated. Finally, it should define the term "multi-functional technology" broadly to cover any software or functionality that is commonly bundled on hand-held devices, and supporting installation, training and maintenance services.

2. Additional Limitations on the Provision of Electronic Prescribing Technology

(a) Promoting Compatibility and Interoperability. CMS solicits comments on whether the safe harbor should protect e-prescribing technology that is used for the transmission of prescribing information on non-drug items and services, such as supplies and laboratory tests, and whether the technology should be required to be interoperable and how this should be defined.

We believe that, as a general principle, the greater the functionality and compatibility of the technology, the greater its convenience and usefulness, and therefore, the more likely that it will be used for all purposes, and the fewer the barriers to the adoption of e-prescribing instead of paper prescribing. As such, the exception should protect technology used for transmission of non-drug items, such as supplies. It is often the case that a physician will want to prescribe a drug and related non-drug item (e.g. insulin and insulin strips and other related insulin supplies) at the same time. It should be at least as convenient and easy for a physician to do this electronically as it is to do it by paper. This will not be the case if the physician has to use one mechanism to prescribe the drug and another to prescribe the non-drug items. Greater functionality, therefore, plays an important role in removing barriers to the adoption of e-prescribing technology.

We strongly support the concept of interoperability and believe that this should be a requirement for e-prescribing technology to qualify under the exception. We agree that this will serve as an important safeguard against fraud and abuse, to the extent the economic incentive exists for a donor to seek to induce referrals. As such, it is

appropriate to prohibit donors or their agents from taking any action to disable or otherwise impose barriers to compatibility. We support the definition of "interoperability" as the "ability of different operating and software systems, applications, and networks to communicate and exchange data." However, we caution against including, as part of the definition of interoperability, the requirement that the technology do so in an "accurate, secure, effective, useful, and consistent manner." While these attributes are clearly important and necessary for effective electronic communication, they go beyond interoperability into the realm of security and into subjective judgments as to what is or is not "effective" or "useful." Adding these requirements to the definition of "interoperability" not only blurs the line between these different concepts, but makes it more uncertain for donors as to whether their technology qualifies. This uncertainty increases the risk level for donors, and makes them less likely to be willing to make a donation, thereby undermining the very purpose of the exception.

Recommendation: The exception should protect technology that is used for the transmission of prescription information about non-drug items and services such as supplies. It should also require that the technology be interoperable, which should be defined as the "ability of different operating and software systems, applications, and networks to communicate and exchange data."

(b) Value of Protected Technology. CMS states that it is considering limiting the value of technology that may be donated by a single donor in order to minimize the potential for fraud and abuse. As such, it requests comments on the amount of, and the methodology for, determining a cap to apply to the donated technology and various other issues related to such a cap.

CMS does not explain how the value of donated technology increases the risk of fraud and abuse, nor how a cap will minimize this risk. It is certainly appropriate that the exception be limited to e-prescribing technology and not protect "all possible costs," and it makes sense that conditions be imposed requiring interoperability. However, there is no reason to believe a fixed dollar limit in any way correlates to or reduces the risk of fraud and abuse and certainly serves no purpose for those donors that have no incentive to induce referrals. Moreover, as stated above, given the demonstrated unwillingness of physicians to commit dollars to e-prescribing, a percentage cap is likely to result in significantly less being spent on e-prescribing technology than is necessary to conduct an effective e-prescribing program. As such, it will serve simply to impede the adoption of e-prescribing technology.

For the same reasons that we do not believe any cap is necessary, we do not believe that CMS should be concerned about the retail vs. non retail value of the technology and the potential to disadvantage smaller donors. Smaller donors, in fact, benefit from the e-

prescribing technology provided by the larger donors. Thus, rather than being at a competitive disadvantage, smaller donors essentially enjoy a "free ride" when larger donors bear most of the burden of building the e-prescribing technology infrastructure that benefits the health care system as a whole.

CMS also requests comments on whether the cap should be reduced over time. As with caps in general, we oppose a cap that would be lowered over time. There is no evidence or reason to believe that simply because e-prescribing becomes widespread, those physicians that have not already migrated to e-prescribing are any more likely to do so on their own. In addition, there will always be new physicians just starting their practices, and while they may understand the benefits of e-prescribing, they are the least likely to have the necessary resources to invest in e-prescribing technology. Indeed, the opposite is more likely, in that those most resistant to changing their prescribing habits from paper to technology are likely to need more assistance and greater support in order to be persuaded to shift. Similarly, there is no reason to believe that physicians that are now unwilling to invest in e-prescribing technology because of its lack of economic pay-off for them are any more likely to do so in the future if the economic imperatives remain the same.

As long as the exception is limited to e-prescribing technology, and that technology is interoperable, the value of the technology donated should not concern CMS. Without the intervention of CMS, it will be limited by the financial and practical constraints of donors as they determine what technology is "necessary" to promote e-prescribing.

Recommendation: CMS should not impose any cap on donated e-prescribing technology, whether based on a fixed dollar amount or percentage, retail or non-retail value, or an amount that is reduced over time.

(c) Other Conditions.

CMS proposes to prohibit donors from conditioning the receipt of the e-prescribing technology on the recipient doing business with the donor. It also proposes to prohibit the donor from taking into account the "volume or value" of the physician's referrals or "other business generated" between the parties and would prohibit "criteria based upon the volume or value of prescriptions written by the physician that are dispensed or paid by the donor, as well as any criteria based on any other business generated between the parties."

We believe that this limitation reflects a fundamental misunderstanding of the business relationship and economic incentives of the parties, and will be a major stumbling block inhibiting the spread of e-prescribing technology. While it is appropriate to prohibit health care providers from basing their donations on the volume of other medical services

referred to them, it is equally fitting and appropriate for donors to consider the prescribing behavior (e.g., volume of prescriptions, total drug cost prescribed) of physicians towards their own patient populations in allocating their e-prescribing donations. Donors have a legitimate interest in seeking to have the impact of reduced medical errors, cost savings and improved efficiencies inure first and foremost to the benefit of their own patient populations. Indeed, this is the very reason donors will consider funding e-prescribing technology, and the legitimate return they expect to see on that funding. Part D plans will especially want to target high-prescribing physicians (measured by drug spend or number of prescriptions) to their patient populations, since it is by changing the prescribing habits of these physicians from paper to e-prescribing that they will see the greatest cost savings, reduction in medication errors, improvement in formulary compliance and administrative efficiencies for their plan participants.

Donors are generally not non-profit entities that may expend their resources on the public good, and it is unrealistic and inappropriate to require that they donate technology for the common good without consideration for the direct impact and benefit to their patient populations. They should be allowed to take that potential impact into account in determining how to expend their e-prescribing budget so as to have the greatest impact on their patient populations in terms of improved clinical safety, quality of care and more cost effective health care services.

Recommendation: Donors should be allowed to target their donations to those physicians whose adoption of e-prescribing technology would have the greatest impact on the donor's patient or plan participant population in terms of reduced medication errors and improved efficiency. Thus, donors should be allowed to take into account the volume or total drug costs of prescriptions written for the donor's population, and to otherwise direct their donations in such a manner as to be able to reap the greatest benefit for their patient or plan participant population.

We appreciate the opportunity to provide these comments, and look forward to working collaboratively with Administration to promote the rapid adoption of e-prescribing technology for the benefit of the entire population. If you have any questions, or would like discuss our comments please do not hesitate to contact Wendy Parker, Vice President Federal Relations for Caremark, at 202-772-3517.

Sincerely,

Wendy C Parker

Wendy Parker
Vice President, Federal Relations

DEC -9 2005

eHEALTH INITIATIVE
Real Solutions, Better Health

December 12, 2005

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

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

Dear Dr. McClellan:

Enclosed please find the comments of the eHealth Initiative ("eHI") with respect to the Centers for Medicare & Medicaid Services' ("CMS") proposed federal physician self-referral ("Stark") law exceptions for arrangements involving electronic prescribing and electronic health records ("eHR") arrangements. eHI appreciates the opportunity to comment on the proposed rule.

eHI is a non-profit organization whose mission is to improve the quality, safety and efficiency of health care through information and information technology ("IT"). Among its over 200 members, eHI represents the following stakeholders in the healthcare community, each of whom has a strong interest in improving the healthcare system through the use of interoperable IT systems:

- Accrediting groups and quality improvement organizations
- Consumer groups
- Electronic transactions services companies
- Employers and purchasers
- Group purchasing organizations
- Health care information technology suppliers
- Health systems, hospitals, and other healthcare organizations
- Laboratories and ancillary services providers
- Medical device manufacturers
- Payers and other risk-bearing institutions
- Pharmaceutical manufacturers
- Practicing clinicians and physician groups
- Public health organizations
- Research and academic institutions
- Standards organizations

eHI currently focuses its efforts on reducing barriers to the creation of a more patient-centered, interoperable healthcare system in which providers, patients and those responsible for population health will have secure and appropriate access to the information necessary to improve health and healthcare.

More specifically, eHI focuses on organizing stakeholders and engaging them in change; aligning incentives and securing financing; navigating policy and legal issues; tackling other technical aspects of health information exchange; and driving practice and healthcare transformation to support rapid improvements in healthcare quality, safety and efficiency.

This work is of vital importance to all healthcare stakeholders, particularly patients, who face a fragmented healthcare system where (1) continuity of care continues to be a challenge; (2) quality may be jeopardized due to a dearth of information at the point of care; (3) vital paper data can not be accessed, combined or integrated; (4) providers spend an inordinate amount of time searching for and organizing information; and (5) potential gaps exist between what clinicians do and the latest evidence-based protocols.

Key leaders across our nation – including President Bush, the U.S. Congress, and others at the highest levels of the Federal government – recognize that healthcare IT ("HIT") has enormous potential to mitigate these systemic challenges by improving the quality of care, easing navigation within the healthcare system, enabling appropriate point-of-care and longitudinal access to integrated healthcare data, saving money and – most importantly – saving lives.

Providers, hospitals and other healthcare entities are examining potential ways to incorporate HIT into the practice of medicine but face a myriad of barriers, including the Stark and anti-kickback laws. On the one hand, CMS' proposed exceptions represent progress towards removing these barriers, providing important guidance and leadership in the effort to increase the use of HIT and improve the healthcare system for patients and those that care for them. Indeed, the proposed exceptions acknowledge and address head-on two primary policy barriers that impede the spread widespread adoption of HIT and health information exchange: the misalignment of incentives and the issue of standards and interoperability. On the other hand, and as reflected in the enclosed comments, eHI believes that vital and significant work remains to be done if CMS is to strike the appropriate balance between (1) combating healthcare fraud and abuse and (2) providing useful, workable exceptions that will encourage the innovation and adoption of HIT.

Thank you again for the opportunity to participate in this important process. eHI would welcome the opportunity to discuss these issues with you should you desire or require additional information.

Sincerely,

Janet Marchibroda

Janet Marchibroda
Chief Executive Officer
eHealth Initiative

Comments by the eHealth Initiative on CMS' Proposed Stark Law Exceptions for Electronic Prescribing and eHR Arrangements

Overview

eHI is an organization composed of healthcare stakeholders interested in improving healthcare safety, quality and efficiency through information and information technology. eHI's diverse membership has recently approved a set of principles specifically addressing any new Stark and anti-kickback law exceptions and safe harbors proposed by the Federal government. These principles, which both underlie and guide our organization's specific comments on CMS' proposed rule, are set forth below. For purposes of these comments, eHI wishes to highlight in particular the first and fifth principles, which (1) focus on encouraging collaborative HIT sharing models and how to encourage interoperability using a standard electronic format and (2) recognize the evolving nature of standards and interoperability processes.

eHI Common Principles - Stark and Anti-Kickback Law Exceptions

1. Any new exceptions and safe harbors should encourage collaborative models for sharing health information technology.

2. There should be no automatic sunsetting of new exceptions and safe harbors.

3. The definition of permitted support (nonmonetary remuneration) under a new exception or safe harbor should include: provision of any equipment, item, information, right, license, intellectual property, software, training, education or service used for developing, implementing, operating or facilitating the adoption of electronic health records and the electronic exchange of health information for those providers. Permitted support should not hinder a physician or other health care provider from engaging in community health information exchange or limit or restrict the use of health information technology in conjunction with other health information technology. Open networks should be encouraged.

4. Federal fraud and abuse protections should pre-empt state laws that prohibit kickbacks and physician self-referrals as applicable to HIT and that specifically conflict with the principles laid out in this document.

5. Safe harbor provisions should encourage interoperability using a standard electronic format and recognize evolving nature of standards and interoperability processes. For purposes of this paragraph, the term standard electronic format means a format using open electronic standards that--
   (A) enable health information technology to be used for the collection of clinically specific data;
   (B) promote or provide for the interoperability of health care information across health care settings, including reporting under this paragraph and to other Federal agencies; and
   (C) facilitate clinical decision support, and such standards may include those developed or recommended by the Office of the National Coordinator for Health Information Technology, the Consolidated Health Informatics Initiative, or the American Health Information Community.

Electronic Prescribing Exception: § 411.357 (v)

Designated Health Services Entities Protected by the Exception – CMS solicits comments on whether there is a need to protect other categories of donors or recipients, beyond those specifically set forth in section 1860D–4(e)(6) of the Social Security Act, and if so, how best to address protection for those individuals or entities.

Consistent with a key goal of the proposed rule – interoperability – eHI believes that the list of donors should be expanded to specifically include clinical laboratories and other types of health care providers such as nursing homes, community health centers, etc. Indeed, if CMS expands the type of technology that may be donated – to include, for example, e-prescribing technology that is used to transmit prescription information regarding items that are not drugs, such as lab tests, or to include multi-functional technology – then it would be unfair to permit the currently proposed donors to provide such expanded other types of technology, but to restrict other health care providers from providing any technology, especially when it relates to the performance of their business (e.g., lab ordering and results software). In addition to creating an uneven playing field, which we do not believe Congress intended, this approach would impede the progress and forward momentum CMS should be working towards with respect to both e-prescribing and electronic health records.

Regarding physicians specifically, first, eHI believes that the list of donors should be expanded to permit group practices to donate electronic prescribing and eHR technology to other physician practices. Given that larger group practices are at the fulcrum of the health care delivery system in many communities around the nation, these entities should be afforded the same exception as hospitals, with, of course, the same limitations. Second, we recommend that CMS clarify or amend the proposed rule language to ensure that all physicians in a medical group can fully utilize items and services donated by a hospital. This change recognizes the practical and market reality of medical groups today: that they operate often as a unit, in which all physicians and other clinicians in the practice access the same HIT.

Finally, CMS should also provide for periodic evaluation and updating of permitted donors, given the rapidly evolving nature of HIT and electronic health information exchange.

Protected Nonmonetary Remuneration – CMS' proposed definition of necessary nonmonetary remuneration includes hardware, software, broadband or wireless Internet connectivity, training, information technology support services and other items and services used in connection with the transmission or receipt of electronic prescribing information. eHI recommends that this definition specifically include connectivity services, help desk services and operating system software. Inclusion of items such as these will support the optimum use of information technology without adversely impacting the fight against fraud and abuse. (eHI also recommends that hardware be included under both the e-prescribing exception and any her exception.)

eHI also recommends that hardware be included under both the e-prescribing exception and any eHR exception.

Promoting Compatibility and Interoperability – CMS defines the term "interoperable" to mean the ability of different information systems, software applications and networks to communicate and exchange information in an accurate, secure, effective, useful and consistent manner and solicits public comment on this approach.

Interoperability and standards-based health information exchange is a bedrock of eHI's organizational principles, mission and work. It propagates the mobilization of healthcare data electronically across systems, which eHI believes is the key to realizing the full value of improving quality, saving lives and reducing costs by providing information about the patient when and where it is needed most – at the point of care. As noted above, interoperability also is specifically called for in eHI's common policy principles relating to new physician self-referral and anti-kickback law exceptions and safe harbors, which state that:

- Any new exceptions should encourage interoperability using a standard electronic format and recognize the evolving nature of standards and interoperability processes.

- Any new exceptions should encourage collaborative models for sharing health information technology.

eHI would ask CMS, in reviewing its definition of interoperability, to take these principles into account, as well as specific consensus-based definitions of interoperability already existing today from HL-7, the National Alliance for Health Information Technology (NAHIT) and the definition of interoperability published in the January 18, 2005 collaborative Office of the National Coordinator for Health Information Technology (ONCHIT) RFI Response, endorsed by 13 major health and information technology organizations including eHI. These three definitions are detailed below.

The HL-7 definition of interoperability is the ability of two or more systems or components to exchange information and to use the information that has been exchanged accurately, securely, and verifiably, when and where needed.

The NAHIT definition of interoperability is the ability of different information technology systems and software applications to communicate, to exchange data accurately, effectively and consistently, and to use the information that has been exchanged.

The term interoperability in the Collaborative ONCHIT RFI Response has three distinct components, each of which must be present to enable full participation:

- At the I/T network access level (here meaning the Internet), interoperability means the capacity to physically connect a sub-network user to the network for the purpose of exchanging data over its components with other users.
- At the network authentication level, interoperability consists of the ability of a connected user to demonstrate appropriate permissions to participate in the instant transaction over the network, based on demonstrating appropriate authentication(s) of user and subnetwork identity as a privileged party;
- At the application level, interoperability means the capacity of a connected, authenticated user to access, transmit and/or receive/exchange usable information with other users. The interoperability standard must support the full spectrum from uncoded and unstructured data to highly structured and coded semantics. Therefore, at the application level, there will be a hierarchy of coexisting interoperability information standards to accommodate the varying needs and sophistication of the user information exchange.

Collectively, these definitions provide additional insight into what comprises the interoperability concept and the goals it should aim to achieve, which are vital in CMS' proposed rule.

Value of Protected Technology – CMS considers in the proposed rule whether to limit the aggregate fair market value of all items and services provided to a physician from a single donor and states its belief that a monetary limit is appropriate and reasonable to minimize the potential for fraud and abuse.

eHI does not support a dollar cap or other limit on the aggregate fair market value of all items and services provided to a physician from a single donor. In our view, such a limitation is (1) not necessary, may be difficult to formulate with a specific dollar figure (indeed the value of items and services may be perceived quite differently depending on whether the value is calculated in terms of donor's actual cost or as the value to the receipient receiving the items and serves at issue), and (3) would unnecessarily discourage donors from providing items and services.

If CMS does opt to adopt a limit or monetary cap, eHI believes this cap should reflect an appropriately expansive limit and adequately accommodate both the value and costs of items and services.

Finally, eHI would like to emphasize that many physicians already possess items or services used for e-prescribing, which were purchased at fair market value. These "early adopters" who have already expended the effort and resources to implement health information technology that improves patient care would be penalized under the current proposed rules because they already possess the items or services that the permitted donors would be offering for no charge and thus could not make the certification that the items and services are not technically or functionally equivalent to items and services the recipient already possesses or has obtained. These "early adopters" with preexisting software (whether obtained for free or at a cost) should be rewarded with the same opportunity to benefit from donation opportunities as other providers. Therefore, permitted donors of e-prescribing items and services and should be allowed to offer the e-prescribing component without charge from the effective date of the final rules.

Pre-and Post-Interoperability Exceptions: § 411.357(w) and §411.357(x)

Simplification – In general, eHI believes that the pre- and post-interoperability exceptions (applying to her technology donated before HHS adopts product certification criteria and after, respectively) should be replaced by requirements that more simply and rationally recognize the evolving nature of information technology tools, standards and interoperability that will underlie them. Several of eHI's more specific concerns are discussed below.

Definition of eHR – The proposed rule states that in order to protect against program abuse, CMS is considering including in the final regulations a definition of "electronic health records" for purposes of the exception and is soliciting comments on how this definition should be drafted.

eHI believes that any eHR definition should provide maximum flexibility and err on the side of being overinclusive in terms of function and capability, rather than underinclusive, given that the potential exceptions seek to encourage behavior and practices that will save lives. If CMS adopts a restrictive eHR definition, it may be limiting the exception's health-enhancing and life-saving potential. An example of a broad eHR definition is one that would include hardware, software, network, training and support and would enable embedded clinical support tools to measure quality, safety and efficiency measures and the connectivity to support required measures and interface capabilities. CMS may want to consider eHR technology that meets AHIC functionality, interoperability and security standards, as eligible for protection under the exception.

Benchmark Survey and Evaluation - Consistent with its common safe harbor principles (set forth above), eHI recommends that a benchmark survey and evaluation of the proposed rule and its effects be conducted two years after its effective date and on an annual basis thereafter. In carrying out the study, CMS should consult (1) the OIG another appropriate HHS agencies, (2) the Medicare Payment Advisory Commission, (3) representatives of providers and other stakeholders subject to the rule, (4) the Government Accountability Office, and (5) experts in health care economics and delivery. Based on the results of this study, CMS can propose additions, deletions, or modifications to the proposed exceptions.

Conclusion

eHI commends CMS for its efforts through this proposed rule to achieve an important milestone on the road to President Bush's goal that the majority of Americans to have electronic health records in ten years and for contributing to the growing body of thought on how to transform the healthcare system as we know it. As eHI has emphasized in the above comments, however, much remains to be done to strike the appropriate balance in the proposed rule between combating healthcare fraud and abuse and providing useful, workable exceptions that will encourage the innovation and adoption of HIT.

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DEC -9 2005

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December 9, 2005

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

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

Dear Dr. McClellan:

Premier appreciates the opportunity to comment on the proposed rule on exceptions under the Medicare and Medicaid physician self-referral laws for non-monetary donations to physicians to promote the adoption of health information technologies.

Premier is a strategic alliance of approximately 200 independent, not-for-profit health systems that operate or are affiliated with more than 1,400 hospitals and other health care sites nationwide. Our comments primarily reflect the concerns of Premier's owner hospitals and health systems, which are at the forefront in the adoption of health information technologies (HIT) to prevent patient errors, promote better coordination of care, and improve health care quality.

First, we would like to commend the Centers for Medicare and Medicaid Services (CMS) for publishing proposed rules that go further than those required by the Medicare Modernization Act of 2003 (MMA), which only required establishment of an exception under the self-referral laws for non-monetary donations of e-prescribing technologies.

Using its regulatory discretion, the agency has also proposed two sequential exceptions for donations to promote the use of electronic health records (EHRs) by physicians, one to be effective before the adoption of uniform Federal standards for interoperability and another to apply after the adoption of such standards.

Although these proposed exceptions are steps in the right direction, we are nonetheless concerned that, as currently crafted, they will fall short of achieving their stated objectives. Our primary concerns are outlined below.

Electronic Prescribing Exception: § 411.357(v)

First, the proposed rule is unclear about when multi-functional technologies – including software, hardware, and connectivity services – are protected from sanctions under the self-referral laws. The preamble indicates that CMS is proposing to permit the donation of such technologies in some circumstances as long as the ancillary functions do not become more important than the functions the proposed rule is intended to promote: e-prescribing and EHR.

However, the test for whether such technologies meet this requirement is articulated in different ways for hardware and software. In a discussion of hardware and connectivity services in relation to e-prescribing, CMS indicates that the function of e-prescribing must be a "substantial use" of the donated technology (p. 59185, column 2), but does not define what this means. In a discussion of post-interoperability EHR software, the summary table appearing in the preamble (p. 59184) indicates that the EHR function must be the "core function" of such software, as does the preamble's text (p. 59190, column 1). This term is also undefined, and does not appear in the text of the regulation. The uncertainties created by standards that differ depending on the technology involved, and that include terms that are not carefully defined will discourage donations of such technologies.

Second, the proposed rule would require that a donated item or service – whether an e-prescribing technology or an EHR-related technology -- not be "technically or functionally equivalent to items and services" already possessed by a physician. While the agency includes a brief discussion of these concepts in the preamble to the proposed rule – and indicates that this requirement would not "preclude upgrades of equipment or software that significantly enhance the functionality of the item or service", this does not provide sufficient guidance on this matter to ensure that a donation falls within one of the proposed exceptions. This will present a problem not just for hospitals, but for physicians receiving the donation, who are required to certify that it meets this requirement.

Third, the proposed rule would limit donations by a hospital to physicians who are members of its medical staff "who routinely furnish services at the hospital". CMS indicates that this requirement is intended to prevent hospitals from offering inducements to physicians who practice at other hospitals to join the medical staff of the hospital offering a technology donation. Unfortunately, this requirement would preclude hospitals from making such donations to physicians in the community who refer patients to them, but may not furnish services at the hospital because of the advent of physician specialties, such as hospitalists, who assume responsibility for the day-to-day care of a patient while he or she is in the hospital. It would also seem to preclude donations to physicians who refer patients to hospitals for outpatient diagnostic services furnished by others at the hospital. Yet, in all these cases, it may be very important for community physicians to have a ready means for exchanging information with the hospital and with physicians providing services in the hospital inpatient or outpatient settings, and thus it would make sense for hospitals to donate e-prescribing or EHR-related technology to such community physicians.

Fourth, although it does not specify any amounts or fixed methodology, the proposed rule indicates that CMS intends to establish one or more caps on the value of donated technologies. Although such limitations may be appropriate at some point in the future, the need for continuing investments by hospitals in technologies – HIT and other -- for their own operations will constrain the resources available to donate technologies to physicians for the foreseeable future and will make any caps unnecessary in the near term.

However, if CMS includes a cap in its final rule, Premier urges the agency to use the actual costs incurred by a hospital in acquiring a donated technology to determine its compliance with the cap, rather than applying a test of fair market value, which itself may be expensive for a hospital to determine. Unlike cost-based reimbursement systems – where externally determined upper limits on reimbursable costs may

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create incentives for efficiency and economy – in this context there is no incentive for hospitals to overpay for donated technologies and every incentive for them to constrain their costs. In addition, if CMS decides to adopt a cap, we would encourage the agency to set that cap at the highest possible level; otherwise, the new safe harbor may fail to accomplish its intended goals.

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

Many of the preceding comments obviously apply to both the e-prescribing and the EHR-related portions of the proposed rule. In addition, although Premier appreciates CMS' initiative in proposing an exception for donations of EHR-related software, we believe that the establishment of sequential, pre- and post-interoperability exceptions is unworkable and may discourage the donation of such technologies until after the issuance of uniform Federal interoperability standards.

Finally, Premier is a member of the National Alliance for Health Information Technology and would like to associate itself with the comments it has submitted on the proposed rule.

Thank you again for the opportunity to comment on the proposed rule. If you would like to discuss our comments further or have any questions, please feel free to call Linda Rouse at 202.879.8005.

Sincerely,

Margaret Reagan
Corporate Vice President
Premier

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RENAL LEADERSHIP COUNCIL

Providers of Quality Care for the Nation's Dialysis Patients

DEC -9 2005

December 9, 2005

VIA Hand Delivery

Centers for Medicare and Medicaid Services
U.S. 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: File code CMS-1303-P

Dear Sir or Madam:

Attached please find an original and two copies of the Renal Leadership Council's comments on the Proposed Rule addressing Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements under the physician self-referral prohibition. 70 Fed. Reg. 59182 (Oct. 11, 2005).

If you have any questions, please do not hesitate to contact me. Thank you.

Sincerely,

Marilyn Yager /ED

Marilyn Yager,
Executive Director

601 Pennsylvania Avenue, NW · North Building, 10th Floor · Washington, DC 20004 · 202/756-3341

RENAL LEADERSHIP COUNCIL

Providers of Quality Care for the Nation's Dialysis Patients

December 9, 2005

VIA Hand Delivery

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
U.S. 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: File code CMS-1303-P

Dear Dr. McClellan:

I am writing on behalf of the Renal Leadership Council ("RLC") to present our members' preliminary views about the October 11, 2005 Proposed Rule addressing Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements under the physician self-referral prohibition ("Proposed Rule"). The RLC is a coalition representing the three largest entities providing dialysis care and services to Medicare beneficiaries: DaVita Inc., Fresenius Medical Care North America, and Renal Care Group. Collectively, these suppliers operate more than 2,700 dialysis facilities in 42 states that provide dialysis care to approximately 200,000 patients.

Since the majority of these patients are Medicare beneficiaries, the issues raised by the Proposed Rule will significantly affect the relationships between nephrology practices and the dialysis clinics operated by RLC members. Coordinating the information sharing between the providers who see and treat dialysis patients in the clinic, emergency department and hospital is a critical step toward improving patient care for this vulnerable population. Interoperable clinic electronic health record systems and dialysis information systems are critical to improving communication among the wide variety of providers that care for these patients, streamlining the ordering processes used to direct and initiate treatment, and continuing to enhance the overall quality of care that patients receive.

1. Electronic Prescribing Exception: §411.357(v)

A. Designated Health Services Entities Protected by the Exception

The Centers for Medicare and Medicaid Services ("CMS") is specifically soliciting comments on whether there is a need to protect other Designated Health Services ("DHS") entities, beyond

those specifically set forth in § 1860D-4(e) of the Social Security Act. Although the Proposed Rule as currently drafted envisions that hospitals and medical groups will be primarily responsible for providing appropriate technology to individual physicians and other prescribing providers, we strongly urge CMS to expand the definition of Donor to include End Stage Renal Disease ("ESRD") suppliers/providers.

ESRD providers, like hospitals and group practices, maintain medical staffs that could use electronic prescribing ("e-prescribing") technology to improve the quality of patient care for this vulnerable Medicare population. Given the wide range of health care providers and settings involved in the treatment of ESRD patients, there is a great need for standardization across the continuum of care. Furthermore, the RLC believes that limiting the scope of the exception to only these providers will create obstacles to the Secretary's overarching goal of interoperability of health care information technology. On the contrary, expanding the permissible Donors to include ESRD providers would further encourage the broad adoption of standardized EHR functionality and interoperability between the physicians' medical practice systems and the ESRD providers' dialysis information systems. In addition, allowing only certain types of providers to donate e-prescribing technology places other similarly situated health care providers that may compete to attract clinical staff, such as ESRD facilities, at a competitive disadvantage. Thus, we recommend that CMS revise the Proposed Rule to include ESRD providers as permissible Donors.

However, if CMS decides not to expand the definition of Donors to include ESRD providers specifically, we recommend that CMS revise the Proposed Rule to protect e-prescribing items and services provided by "other providers that maintain a medical staff pursuant to medical staff bylaws to members of their medical staffs," as long as the other conditions of the proposed exception are satisfied.

B. "Used Solely"

As acknowledged by CMS, hardware and connectivity services are often used for more than one purpose. Accordingly, CMS is exercising its regulatory authority to create an additional exception to protect the provision by Donors of some limited hardware and connectivity services that are used for more than one function, so long as a substantial use of the item or service is to receive or transmit e-prescribing information. The RLC generally supports CMS' proposal to establish this additional exception for multi-functional items and services. However, given the difficulty involved in separating and defining functionality, we recommend that all software, hardware, and connectivity services that are used in e-prescribing and electronic health records ("EHRs") be protected if such system is interoperable and necessary for the purpose of the donation, regardless of whether or not the software, hardware and connectivity services provide functions in addition to e-prescribing and EHR functions.

C. Value of Protected Technology

CMS is considering limiting the aggregate value of the e-prescribing technology that a Donor could provide under the exception. The RLC recommends that CMS not establish a cap on

donated technology. Given the wide range of costs of this type of technology, a cap might force Donors to provide outdated technology or items and services that are less than state-of-the-art. Consistent with the Secretary's stated goals, we believe the incentive should be to provide the best systems available, so providers can operate efficiently and achieve interoperability as soon as possible. A cap is likely to interfere with these goals. From an administrative perspective, given the constant changes in technology, we believe it would be very difficult to assess the value and create an appropriate, consistent cap for the variety of relationships between Donors and Recipients.

D. Additional Limitations – Promoting Compatibility and Interoperability

Currently, the Proposed Rule provides protection to only those items and services necessary and used solely to receive and transmit electronic prescription drug information. We recommend that CMS expand the protected items and services to include "necessary" items and services to conduct e-prescribing transactions of all kinds, including laboratory and dialysis orders. This type of protection is necessary to achieve true interoperability of health care information technology systems.

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

A. Permissible Donors

As discussed above, CMS is specifically soliciting comments on whether there is a need to protect other DHS entities beyond those specifically set forth in the Proposed Rule. Although the Proposed Rule envisions that hospitals and medical groups will be primarily responsible for providing appropriate technology to individual physicians and other prescribing providers, we strongly urge CMS to expand the definition of Donor to include ESRD suppliers/providers.

ESRD providers, like hospitals and group practices, maintain medical staffs that could use EHR technology to improve the quality of patient care for this vulnerable Medicare population. Given the wide range of health care providers and settings involved in the treatment of ESRD patients, there is a great need for standardization across the continuum of care. Furthermore, the RLC believes that limiting the scope of the exception to only these providers will create obstacles to the Secretary's overarching goal of interoperability of health care information technology. On the contrary, expanding the permissible Donors to include ESRD providers would further encourage the broad adoption of standardized EHR functionality and interoperability between the physicians' medical practice systems and the ESRD providers' dialysis information systems. In addition, allowing only certain types of providers to donate EHR technology places other similarly situated health care providers that may compete to attract clinical staff, such as ESRD facilities, at a competitive disadvantage. Thus, we recommend that CMS include ESRD providers as permissible Donors.

However, if CMS decides not to expand the definition of Donors to include ESRD providers specifically, we recommend that CMS revise the Proposed Rule to protect EHR items and services provided by "other providers that maintain a medical staff pursuant to medical staff

bylaws to members of their medical staffs," as long as the other conditions of the proposed exception are satisfied.

B. Value of Protected Technology

As discussed above, the RLC recommends that CMS not establish a cap on donated technology. Given the wide range of costs of this type of technology, a cap might force Donors to provide outdated technology or items and services that are less than state-of-the-art. Consistent with the Secretary's stated goals, we believe the incentive should be to provide the best systems available, so providers can operate efficiently and achieve interoperability as soon as possible. A cap is likely to interfere with these goals. From an administrative perspective, given the constant changes in technology, we believe it would be very difficult to assess the value and create an appropriate, consistent cap for the variety of relationships between Donors and Recipients.

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

A. Permissible Donors

The RLC urges CMS to add ESRD suppliers/providers to the list of permissible Donors. ESRD providers, like hospitals and group practices, maintain medical staffs that could use EHR technology to improve the quality of patient care for this vulnerable Medicare population. Given the wide range of health care providers and settings involved in the treatment of ESRD patients, there is a great need for standardization across the continuum of care. Furthermore, the RLC believes that limiting the scope of the exception to only these providers will create obstacles to the Secretary's overarching goal of interoperability. Expanding the permissible Donors to include ESRD providers would further encourage the broad adoption of standardized EHR functionality and interoperability between the physicians' medical practice systems and the ESRD providers' dialysis information systems. In addition, allowing only certain types of providers to donate EHR technology places other similarly situated health care providers that may compete to attract clinical staff, such as ESRD facilities, at a competitive disadvantage.

However, if CMS decides not to expand the definition of Donors to include ESRD providers specifically, we recommend that CMS revise the Proposed Rule to protect EHR items and services provided by "other providers that maintain a medical staff pursuant to medical staff bylaws to members of their medical staffs," as long as the other conditions of the proposed exception are satisfied.

B. Value of Protected Technology

The RLC recommends that CMS not establish a cap on donated technology. Given the wide range of costs of this type of technology, a cap might force Donors to provide outdated technology or items and services that are less than state-of-the-art. Consistent with the Secretary's stated goals, we believe the incentive should be to provide the best systems available, so providers can operate efficiently and provide the best care possible. A cap is likely to interfere with these goals. From an administrative perspective, given the constant changes in technology,

we believe it would be very difficult to assess the value and create an appropriate, consistent cap for the variety of relationships between Donors and Recipients.

* * *

Thank you for the opportunity to comment on the proposed Stark exceptions for e-prescribing and EHR items and services. The RLC members look forward to working with CMS to finalize the Proposed Rule in a way that allows ESRD providers to continue providing quality care to Medicare beneficiaries and to contribute to achieving the Secretary's goal of interoperable health care information technology systems.

Sincerely,

Marilyn Yager

Marilyn Yager
Executive Director

December 12, 2005

The Honorable Mark W. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
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

Dear Dr. McClellan:

On behalf of the Providence Health System, I want to offer our formal comment to CMS' Notice of Proposed Rulemaking that sets forth new exceptions to the Physician Self-Referral Law ("Stark") regulations for the purposes of facilitating the adoption of technology for e-prescribing medications and electronic health records.

The Providence Health System is a not-for-profit, Catholic health system that includes 18 acute care hospitals, 18 freestanding long term care facilities, clinics and physician groups, a health plan and home health agencies serving communities in Alaska, Washington, Oregon and California. Nearly 40% of the Providence Health System's gross revenue comes from the Medicare program; we are the largest Medicare provider in the states of Alaska and Oregon. While these payments are an important part of the system's revenue, more importantly they enable the provision of services for tens of thousands of Medicare beneficiaries.

The widespread adoption of health information technology, in particular electronic health records, is vital to improve both the quality and efficiency of our nation's health care system and we applaud CMS' efforts, in conjunction with the Office of the Inspector General, to remove significant regulatory barriers to physician adoption of e-prescribing and electronic health record technology. In general, we believe the October 11 proposed rule is a step that will bring us closer to that goal.

In this letter, we offer our perspectives and recommendations to CMS on specific policy proposals made in the October 11th proposed rule. These are:

1. The need for greater clarification on what constitutes "covered technology" for both e-prescribing and electronic health records;

concerned that physicians may intentionally divest themselves of functionally or technically equivalent technology that they already possess in order to shift costs to the DHS entity.

While we agree with the importance of assuring that opportunities for fraud and abuse be minimized, we are concerned that this provision is overly cumbersome and ultimately unnecessary. In our view, it will be difficult for even the most technically-savvy physicians to be proficient at distinguishing computer hardware and making a determination that one product is technically or functionally equivalent to another. We also believe it is unlikely that a physician office that has invested in an electronic health records system or e-prescribing system is likely to fully divest that system in favor of a new one, simply because it is being donated by a partner hospital.

Moreover, CMS does not provide specific criteria – understandably so given the rapid evolution of this technology – to guide recipients on what would constitute equivalence. Accordingly, the burden will fall on the donor hospitals to make that determination, which will hinder the adoption of the technology.

Recommendation:
We urge CMS to eliminate the requirement that physicians certify that they do not possess technically or functionally equivalent items and services; instead, such a determination should be predicated on a good-faith standard for compliance. Further, we urge CMS to develop a clear and consistent standard for what constitutes equivalence to prevent confusion and hesitation on the part of both donors and recipients.

Pre- and Post-Interoperability Period Exceptions for Electronic Health Records
CMS proposes two separate exceptions for the donation of items and services for electronic health records: the first period, pre-interoperability, would allow for a more limited exception for items and services donated before the Secretary's adoption of product certification criteria, including criteria for the interoperability, functionality and privacy and security of electronic health records technology; the second exception period, post-interoperability, would apply to donations made after produce certification criteria are adopted by the Secretary. Appropriately, the post-interoperability exception is broader in the technology covered.

We recognize the need to move cautiously on exceptions for electronic health records in the absence of interoperability certification criteria and applaud the efforts of the Certification Commission on Health Information Technology (CCHIT) toward developing a model certification process. While we support the goal of achieving interoperability, we expect that many, if not most, hospitals will wait until the post-interoperability period to begin making donations of EHR technology to physicians, given the uncertainty of the certification development process, which could take considerable time before it is completed.

Recommendation:

Conclusion
In general, we strongly support CMS' efforts to remove barriers to adoption of electronic prescribing and electronic health records across the health care system. Further, we encourage the agency to consider expanding the list of donors to include other providers not mentioned in the proposed rule, such as long term care facilities, laboratory networks and others. We believe this is good public policy and encourage CMS and the OIG to move quickly to adoption, recognizing the specific recommendations noted above.

Thank you for your consideration of our comments and should you have any questions on these remarks feel free to contact Steve Brennan, Director, Public Policy & Regulatory Affairs at 206.464.4717 or e-mail at steve.brennan@providence.org

Sincerely,

John Koster MD

John Koster, M.D.
Chief Executive Officer
Providence Health System

15

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Jordan J. Cohen, M.D.
President

December 12, 2005

Daniel R. Levinson
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

Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1303-P
PO Box 8010
Baltimore, MD 212440-8010

Dear Mr. Levinson and Dr. McClellan:

The Association of American Medical Colleges (AAMC) welcomes the opportunity to provide comments on the proposed rules, *Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute* (OIG) and E*xceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements* (CMS). The AAMC represents all 125 accredited U.S. allopathic medical schools, approximately 400 major teaching hospitals and health systems, 96 academic societies, and 90,000 clinical faculty. The Association is pleased that in addition to proposing a safe harbor and exception for e-prescribing, as required by the Medicare Modernization Act, the OIG and CMS recognize the need to create safe harbors for the provision of electronic health records (EHRs). However, as will be described below, we have concerns that the proposed safe harbors will not accomplish their goals and may have unintended negative consequences.

General Considerations and Concerns

When the Physician Self-Referral ("Stark") and Anti-Kickback laws were passed, neither lawmakers nor others contemplated a world in which electronic capabilities would be a key to achieving significant improvements in the safety, quality, and efficiency of patient care. Today, physicians, hospitals, health systems, and other entities are starting to be held accountable for quality. Medicare also is beginning to tie hospital payments to the reporting of quality indicators, a trend that is likely to expand. But hospitals and physicians need the proper tools to measure and improve quality. The adoption of EHRs is costly, and is not equally affordable by all sectors of the health care field. Many hospitals are willing to pay some or all of the costs of providing physicians and other

health care providers with EHRs. Many physicians will not spend substantial resources on these tools, especially at a time when they are facing large payment reductions from the Medicare program. The Physician Self-Referral and Anti-Kickback laws have been widely identified as two impediments to widespread EHR adoption.

While the government is not free to ignore statutes, it does have substantial authority to shape regulations to support significant public objectives where the risk of fraud and abuse is minimal. To achieve the goal stated by the Administration, that all Americans will have electronic health records by the year 2014, flexibility must be granted to the donors and recipients of EHRs and e-prescribing software, and to the recipients. In the proposed rules, the OIG and CMS have taken some steps in that direction but significant changes must be made if the government's goal of faster dissemination of EHRs is to be realized.

The OIG has acknowledged the need for a safe harbor for the provision of EHRs, but states in the preamble that "the provision of electronic health records technology to physicians and others poses greater risk of fraud or abuse than the provision of electronic prescribing technology; electronic health records technology is inherently more valuable to physicians in terms of actual cost, avoided overhead, and administrative expenses of an office practice." This assumes that the acquisition of technology at reduced or no cost to the physician will encourage bad behavior. The reality is that as the push for quality grows stronger, and the call for electronic health records becomes more persistent, physicians will have no choice but to adopt electronic technology. For them, even "free" technology will come at a major cost in terms of significant changes in office procedures and the continuing need for support and training related to the software. For these reasons, many physicians are reluctant—if not resistant—to adopt electronic technology. Hospitals, integrated delivery systems, and other possible donors hold the potential to make EHR adoption happen more quickly if the fraud and abuse laws do not stand in their way.

Comments on Specific Proposals

Many of the proposals on which comments are submitted below appear in both the e-prescribing and EHR safe harbors and exceptions proposed by OIG and CMS. The comments apply to all relevant safe harbors and exceptions.

E-Prescribing as Stand-Alone Software. The Medicare Modernization Act (MMA) calls for a safe harbor "solely related to e-prescribing." In the marketplace, it is difficult to find e-prescribing software that is not part of a bundled package offering many other functions. Furthermore, without adequate T1 lines, secure connections, ongoing maintenance and support, and other interfaces, the software is not functional. In some cases, it also may be necessary to supply the hardware. The OIG and CMS should use their statutory authority to expand the exception and recognize that e-prescribing software can be, and most frequently is, an integral part of a more complete package, and the provision of additional items should be covered by the exception and safe harbor.

Although recipients could be charged "fair market value" for the additional functions and items, determining what that amount would be when many of these products are developed and sold as a single unit is impractical. Further, if many physicians do not have the resources to purchase these products, then it is likely that they will choose not to acquire them if they must pay for them. As long as the provision of these items and services is part of the implementation of an over-all national policy goal, and the hospital does not tie provision of the products to a requirement for referrals, providing them free or below cost should be allowed.

Physician Certification. The rules propose that physicians be required to certify that items and services provided are not "technically or functionally equivalent" to those already possessed by recipient. Should a recipient mistakenly certify the lack of equivalency, the consequences could be huge, so fear of incorrectly certifying may become an impediment to physician adoption of EHRs. It seems unlikely that physicians would want to have multiple equivalent systems in their offices, since it would then be necessary to learn and support each system, but deciding on technical and functional equivalency requires a high level of knowledge that is beyond that of most individual physicians. Adding to the difficulty of certification is that even if a system has some equivalent functionality as a stand alone physician office system, it may not be capable of being part of an integrated electronic records. If the certification requirement is retained, the standard should be that the certification is given in good faith. Additionally, the government should provide assistance in determining equivalency.

Donors and Recipients. As proposed, the anti-kickback regulation would apply to donations from a hospital to a physician on its medical staff who routinely furnishes services at the hospital. Some hospitals have other health care professionals, such as NPs and PAs on their medical staffs. Also, some physicians refer patients to hospitals for either inpatient services that are provided by a hospitalist, or for outpatient services provided by a physician on the hospital's medical staff. In either case, the physician does not routinely furnish services at the hospital, but both the referring and treating physicians and the patients would benefit from being able to use an interoperable EHR. Permitted recipients should include <u>all</u> individuals on a hospital's medical staff who routinely furnish services at the hospital as well as physicians and other licensed health care professionals whose patients regularly receive inpatient and/or outpatient care at the hospital or health system.

For both the anti-kickback and "Stark" regulations, the permissible donors should include all components of integrated delivery systems (IDSs). Typically, an IDS consists of a parent entity that owns or controls one or more hospitals, and at least one or more of the following: network providers; an entity that operates and manages the network providers; and/or a physician-hospital organization or physician organization, and all relevant components. Permissible recipients should include physicians and other providers who have contracted with the IDS to provide services, whether or not they are members of the hospital's medical staff.

Publicly Available Software. Comments are requested about whether, and if so how, to take into account recipient access to any software that is publicly available either free or at a reduced priced. Publicly available software is not relevant to the requirements of a safe harbor or an exception. After the Department of Veterans Affairs attempted to make its EHR system (known as VISTA) available for public use, it decided instead to beta test the software at a limited number of sites. Presumably, at some point the software will be made available more broadly. The VISTA system is designed for smaller practices, and it is anticipated that users will incur huge costs associated with upgrades and maintenance.

Hospitals and physicians must be allowed the flexibility to determine which software best meets their needs, as long as it also meets the interoperability standards (once they are available). It should be noted that an advantage of publicly available software is that it may help to "level the playing field," so that in those locations where a hospital does not have the financial ability to pay some or all of the costs for physicians to obtain the software, it can be acquired.

Pre- and Post- Interoperability Rules. CMS wrote, "we believe that interoperability can serve as an important safeguard against fraud and abuse." Whether or not this is true, waiting for interoperability before a meaningful safe harbor is available seems contrary to achieving the objective of widespread dissemination and use of EHRs. The minimal risk of fraud and abuse in a pre-interoperability world must be weighed against the major potential that EHRs hold for improved patient care. Many hospitals and health systems that have the wherewithal to provide physicians with EHRs will not do so because of concerns that they may be seen as violating the fraud and abuse laws. But if adoption of EHRs is a national policy goal, then those in the position of helping to achieve that goal must be given the go-ahead to do so. In our imperfect world, eliminating all risk of fraud and abuse is impossible. Using the fear of prosecution for violation of the fraud and abuse as a barrier to progress is, in our view, untenable.

In lieu of separate pre- and post- interoperability standards, the safe harbor should require that the items being donated can exchange health care information in compliance with standards once adopted by the Secretary, and that nothing may be done to the items that would pose a barrier to this information exchange. Any services provided under the safe harbor or exception must be in support of those items.

If the final rule contains the pre- and post- operability distinction, then the standards must be adopted simultaneously to allow hospitals to plan effectively.

Setting a Cap on the Value of the EHR. At this time insufficient information is available to set a reasonable per physician or provider cap on the value of the items and services that may be provided. If a low cap is established, it may discourage the provision of EHRs. If a high cap is established, hospitals may feel pressured to provide the maximum amount allowable. There is no definitive evidence that a cap

will prevent fraud and abuse, though an incorrectly set cap may have adverse consequences for EHR dissemination. The best approach is to monitor this issue. If in the future it becomes apparent that a cap should be set, then the government should establish one.

Issuance of an Anti-Kickback EHR Safe Harbor

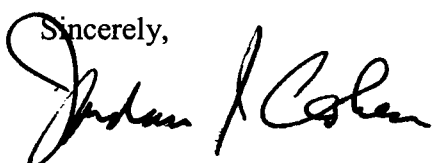
The AAMC is concerned that rather than proposing actual regulatory language for comment and review, the OIG has chosen to pose many issues that need to be resolved before a safe harbor can be developed. We recognize the need for hospitals, physicians, and others to be given clarity about the rules that govern the provision of EHRs, and understand that this must be done as quickly as possible. Also, as stated previously, the Anti-Kickback Safe Harbor must be consistent with the "Stark" exception for EHRs. However, we believe that it would be premature for the OIG to proceed to a final EHR safe harbor. What appears in the *Federal Register* is akin to an Advanced Notice of Proposed Rulemaking and not a proposed rule, so it should yield sufficient valuable comments and information to allow the OIG to proceed to the next step. The OIG should be committed to issuing a proposed rule as soon as the comments are analyzed, and to publishing a final rule shortly thereafter. Alternatively, the OIG could issue an interim final rule with a comment period. For a safe harbor that encourages EHR dissemination, time is of the essence.

It is extremely important that the safe harbor parallel CMS's "Stark" exception for EHRs. Any conflicts between the safe harbor and the "Stark" exception would discourage their use, and could further delay the widespread dissemination of EHRs.

The AAMC also endorses the letters submitted by the National Alliance for Health Information Technology and Partners HealthCare System.

If you wish to discuss these comments further, please contact Ivy Baer of my staff at 202-828-0499.

Sincerely,



Jordan J. Cohen, M.D.

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December 12, 2005

VIA HAND DELIVERY

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

RE: Comments to Proposed Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute

To Whom It May Concern:

On behalf of CBLPath, Inc., a specialized anatomic pathology laboratory providing pathology services to patients of physician practices around the nation, we appreciate the opportunity to present our comments on the proposed safe harbors for electronic prescribing arrangements and electronic health records ("EHR").

Comment 1

For the reasons set forth below, we would appreciate the OIG's clarifying that the proposed safe harbors have not been developed to address software interfaces between ancillary service providers and ordering physicians as further described below and that such interfaces should continue to be reviewed under a traditional anti-kickback analysis.

In an effort to improve the quality and efficiency of health care we provide to our patients, we had begun investigating how to facilitate more accurate and efficient communication between laboratories and ordering physicians while maintaining compliance with the Anti-Kickback Statute. As part of that process, we considered whether a laboratory could provide a software interface between the laboratory and an ordering physician. These interfaces would allow the physician to order laboratory tests and to receive test results electronically. Because patient information is electronically transmitted to the laboratory along with the order for the test, the laboratory is not required to manually re-enter the patient information into its system. Therefore, the number of transcription errors, and costs associated therewith, is significantly reduced. The software interface also allows the laboratory to send test results to the ordering physician

electronically and routes the results directly into the correct patient's electronic health record maintained by the physician's office.

The electronic interface between the physician practice's EHR and the ancillary provider's systems primarily benefits the ancillary service provider through the elimination of transmission costs and transmission errors. As a result, the physician practice has little incentive to cover the expenses associated with the development and installation of such interfaces.[1]

We do recognize that the physician practice will enjoy some incidental benefit in the improved efficiencies recognized by the elimination of the filing of paper reports from the ancillary provider; however, we would encourage the OIG to recognize the policy benefits of the elimination of potential misfiling and loss of reports, as well as the increased efficiencies recognized for all providers. In addition, electronic interfaces can materially increase the speed at which reports can be transmitted and accessed by the physician and ultimately delivered to the patient.

To limit potential incidental benefits to the physician practice, we would suggest that the interface supplied by the ancillary service provider be limited to prevent use by third parties and would be used only for the transmission and receipt of information between the ancillary service provider and physician practice. This would limit the incidental benefit of receiving or transmitting information to and from other referral sources.

Pathology laboratories, and other ancillary service providers, have historically relied on existing guidance from the OIG when providing free or discounted items of value (such as computers or facsimile machines) to referral sources. That guidance is best summarized in preamble comments to the safe harbor regulations issued in 1991:

> A related issue is the practice of giving away free computers. In some cases the computer can only be used as part of a particular service that is being provided, for example, printing out the results of laboratory tests. In this situation, it appears that the computer has no independent value apart from the service being provided and that the purpose of the free computer is not to induce an act prohibited by the statute . . . .

The OIG's analysis regarding the provision of free items such as computers or facsimile machines, hinges on whether the free item has independent value to the referral source such that it raises an inference that one purpose of the "gift" is to induce referrals in violation of the Anti-Kickback Statute. Based upon language in Advisory Opinion 98-16 and the proposed rule, the OIG considers avoided overhead and administrative expenses in determining whether an item or service has independent value to the referral source. In summary, so long as the free item or

[1] In fact, in many situations a Donor may have a business competitive reason to limit interfaces with ancillary service providers if the Donor also provides such ancillary services.

service is not intended to induce referrals and does not have independent value apart from the service being provided, there is not a violation of the Anti-Kickback Statute.

We do not believe that the proposed electronic prescribing or electronic health records safe harbors reach, or are intended to reach, the type of interfaces described above. The interface between the laboratory and ordering physician would work in conjunction with the ordering physician's existing EHR system. The laboratories would not be providing referral sources with electronic prescribing or EHR software that could be used by referral sources for any purposes other than those directly related to the transmission of information between that laboratory and the ordering physician. Therefore, we would appreciate the OIG's clarifying that the proposed safe harbors have not been developed to address these types of interfaces and that such interfaces will continue to be reviewed under a traditional anti-kickback analysis as set forth below.

Comment 2

We believe that the categories of Donors and Recipients protected under the proposed electronic prescribing arrangements safe harbor should not be expanded to include ancillary service providers such as laboratories.

For the reasons discussed in Comment 1 above, we also believe that the categories of Donors and Recipients should not be expanded to include ancillary service providers. Including ancillary service providers as a category of Donor appears to contradict the OIG's longstanding position with regard to the provision of free items or services. And, as the OIG states in the proposed rule, even after an interoperable network becomes functional, "parties may use the offer or grant of free technology itself as a vehicle to capture referrals." Further, we believe that limiting the categories of protected Donors and Recipients is preferable to limiting what items and services can be electronically prescribed. Allowing a broader range of items and services than just prescription drugs to be electronically prescribed is consistent with the President's goal of "achieving widespread adoption of interoperable electronic health records for the purpose of improving the quality and efficiency of health care." Therefore, we believe that continuing to limit the categories of Donors and Recipients to those already identified is appropriate.

As has been stated by the OIG on a number of occasions, the competitive ancillary provider market has often abused the provision of free or discounted items of value to referral sources. Abusive providers who are willing to engage in such practices results in an unfair marketplace for compliant ancillary service providers. We therefore encourage the OIG to clearly state its position on ancillary service providers' use of this safe harbor and would also encourage the OIG to explain how it would analyze the provision of EHR technology under the traditional anti-kickback analysis.

Comment 3

We believe that, consistent with the goal of improving health care, the proposed electronic prescribing safe harbor should be expanded to include prescribing items and services beyond prescription drugs.

We applaud the government's efforts to promote the adoption of interoperable electronic prescribing and EHR technology that will significantly improve the quality and efficiency of health care in the United States. We believe that, consistent with the goal of improving health care, the safe harbors should not be limited to electronic prescribing of prescription drugs. Instead, we believe that the safe harbors should protect qualifying electronic prescription technology used to transmit prescription information for prescription drugs, as well as items and services that are not drugs, including supplies and laboratory tests. Our support for extending the safe harbors to protect the transmission of non-prescription drug information is conditioned upon the continued limitation of the Donors and Recipients protected under the rule as currently proposed.

Comment 4

We agree that the provision of EHR technology presents heightened risks and, therefore, any pre-interoperability safe harbor for EHR technology should not expand the category of Donors to include coverage of ancillary service providers such as laboratories.

We agree that Donors should be limited to hospitals, group practices, PDP sponsors and MA organizations. Laboratories such as ours are extremely interested in improving the health and safety of all of our patients. Nonetheless, we agree that ancillary service providers do not have a stake that is comparable to the Donors identified above and, as compliant participants in this marketplace, recognize the OIG's concern with abusive practices. The limited categories of Donors identified by the OIG in the proposed rule each have clearly identifiable interests in providing the electronic prescribing and EHR technology to the identified Recipients. We believe that it is the existing relationships between hospitals and their active medical staffs or group practices and their members that serve to protect these arrangements from fraud and abuse concerns. In the proposed rule, the OIG points out that in the past ancillary service providers have used the provision of free or discounted goods with independent value to referral sources in order to induce referrals. However, we do not believe that past improper behavior is sufficient reason standing alone to exclude ancillary service providers from protection under the proposed safe harbors. Instead, we think a more appropriate reason not to include ancillary service providers in the category of Donors would be based upon the fact that any common interests and relationships between ancillary service providers and referral sources is more tenuous, thus leaving more room for improper motives to play a role in the provision of these technologies.

Comment 5

We believe that the categories of Donors or Recipients should not be expanded to include parties beyond those identified above even after post-interoperability standards have been adopted.

We share the OIG's concern that parties might "use the offer or grant of free technology itself as a vehicle to capture referrals," even after interoperability standards have been adopted. However, we do not agree that interoperability standards will sufficiently mitigate the risks so that different safe harbor conditions are appropriate. Therefore, we believe that the categories of Donors or Recipients should not be expanded to include parties beyond those identified above even after post-interoperability standards have been adopted.

We appreciate the opportunity to provide our comments on the proposed rule and look forward to participating in the adoption of electronic prescribing and EHR.

Sincerely,

Michael R. Hess

Cc: William Curtis, CBLPath, Inc.

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DEC 13 2005

GE Healthcare

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.

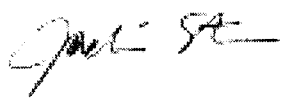
Government mandated interoperability standards will always lag product and market innovations, which is why GE believes that interoperability requirements must be driven by predicating the receipt of government financial and regulatory incentives on conditions that demand interoperability in practice.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

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.

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December 9, 2005

VIA FED EX

The 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, MD 21244-1850

RE: CMS – 1303 – P

Dear Dr. McClellan:

Thank you for the opportunity to comment on the proposed regulations creating exceptions to Section 1877 of the Social Security Act (the so-called "Stark Law") for certain electronic prescribing ("ePrescribing") and electronic health record ("eHR") arrangements.

The cautionary approach adopted in the proposed regulations suggests that the Department of Health and Human Services is operating under two closely related assumptions: (1) eHR and ePrescribing systems are inherently, tangibly valuable to physicians; and (2) physicians will be eager to use eHR and ePrescribing systems if the technology is donated to them.

We challenge the assumption that eHR and ePrescribing technology is inherently or tangibly valuable to physicians. Electronic systems for prescribing and medical record maintenance merely replace existing systems within physician offices. It is by no means clear that physicians perceive **any** benefit to replacing existing systems with their electronic counterparts. The more immediate and tangible benefits of these systems –

improved quality and efficiency of patient care, and safer and easier migration of patients from one provider to another – inure directly to patients, and only indirectly to physicians. It remains entirely unclear if physicians will avoid any costs by maintaining an eHR system as opposed to a paper-based system, and physician cost savings are also highly uncertain for ePrescribing technology.

Physicians will deploy eHR and ePrescribing systems only if they perceive that these systems will benefit them. Even if physicians can avoid making the capital investment needed for electronic systems, physician offices will inevitably bear the principal data input and data maintenance burdens. Since most patient encounters with the health care system occur in physician offices, the burden of data entry and record upkeep for an electronic medical record system will fall disproportionately on physician offices. But physicians do not perceive much value in an electronic medical record system and their perceptions may be justified: Only 11% of the savings available from electronic medical record systems flow to hospitals and physicians combined, with the rest accruing to health plans and insurers. (*The Economist,* 30 April 2005)

Accordingly, there is no reason to believe that physicians will eagerly adopt ePrescribing or eHR systems, even if the technology is donated to them. Unfortunately, physicians have been and will remain reluctant participants in the transition from paper-based to electronic systems. And while certainly an impediment, the cost of the technology has not been the only obstacle. Rather, physicians have been just as reluctant to invest time and energy into these systems as capital. Though we applaud CMS for proposing these limited exceptions to the Stark Law that will allow entities more willing to invest in the necessary ePrescribing and eHR systems to donate certain items and services to physicians, we caution that receiving eHR and ePrescribing technology is unlikely to be sufficient to encourage physicians to transition to electronic systems. Since the new eHR exception will still require physicians to invest in critical hardware and other components of an eHR system, it is likely to be only minimally effective in encouraging eHR deployment.

The concepts of eHR and ePrescribing are not new; the health care community has been aware of the vast potential of these important technologies for some time. Their failure to proliferate suggests that their value and attraction to physicians have been overstated, greatly complicating governmental and provider efforts to develop and implement electronic systems.

We believe that these two erroneous assumptions have led CMS to overstate the risk of fraud and abuse that might accompany the donation of eHR and ePrescribing technology, particularly where the technology is fully interoperable. The proposed exceptions appear to assume that not only will physicians happily accept and implement donated technology, but that they will be so grateful for the opportunity to transition to electronic systems that they will remain loyal to the entity that donated the technology. The reality is that absent additional incentives, physicians are unlikely to transition to electronic formats even if all of the technology is donated to them.

If CMS is committed to the goals of widespread adoption of interoperable eHR and ePrescribing technology, then CMS must reduce the regulatory barriers confronting entities willing to invest in the development and implementation of these systems by expanding the proposed exceptions. We suggest the following:

Expand Permissible Donors and Recipients

Donors

While it makes sense to limit the potential donors of ePrescribing and eHR technology to entities involved in the direct and primary care of patients, it is unclear why the list of potential donors by provider-type was nonetheless limited to hospitals and medical groups. All institutional providers have an interest in ensuring that patient care provided at their facilities benefits from a complete medical record, easily transferred to the facility. There are other entities, such as ambulatory surgical centers ("ASC"), that are as directly and primarily involved in patient care, and who may well be in a good position to further the deployment of eHR and ePrescribing technology to members of their medical staffs. We see no reason to draw a distinction between a hospital providing eHR technology to surgeons who perform procedures at the hospital, while excluding ambulatory surgical centers from providing eHR technology to physicians who perform surgeries at the center. We do not see a need to regulate the types of providers who are eligible donors.

Recipients

At many places, the Preamble explains that the purpose of the proposed exceptions, particularly the eHR exceptions, is to promote open, interconnected, interoperable eHR and ePrescribing technology to improve health care quality and efficiency through, among other benefits, maximally portable health records. To achieve this laudable goal, we strongly urge you to extend the list of eligible recipients of donated

technology to include all physicians and medical groups who share patients with the donating entity.

As currently conceived, the exceptions permit hospitals to donate ePrescribing and eHR technology only to members of their medical staffs. Medical groups are similarly limited by restricting potential donors to physicians who are members of that medical group.[1] While the donated technology might make access to records more efficient and convenient, the proposed regulations do not further the goal of maximizing portability of records. They seem to protect only arrangements with physicians who already have access to the records of the donating entity: Members of medical staffs already have access to hospital records, and medical group members already have access to medical group records. However, a primary care physician who is not a medical staff member may regularly have patients who are hospitalized. Medical records maintained by that primary care physician may never be incorporated into the hospital's medical records system. Hospitals should be free to donate eHR and ePrescribing technology to physicians who are so situated. To achieve maximum portability, eHR networks need to include all providers involved in the diagnosis and treatment of the patient regardless of whether the provider is a member of a particular group or a hospital's medical staff.

In the ordinary course of care, from onset of symptoms to completion of treatment, a patient will likely see multiple unaffiliated, unrelated physician-providers. For instance, in the case of a hospital patient undergoing cardiac surgery, the patient will encounter multiple physician-providers[2] ranging from his or her primary care physician, a cardiologist, a radiologist, a cardiac surgeon, an anesthesiologist, and perhaps a rehabilitation medicine specialist. Each of these providers will have important patient information that the other physicians will need in the course of diagnosis and treatment. The value of an eHR system is not that providers who otherwise have relatively expedient access to patient records are able to obtain those records more efficiently. Rather, eHR benefits patients by facilitating instant access to health records to which a provider might

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1 We fail to see why an exception is needed to permit a medical group to purchase and maintain an eHR or ePrescribing system. Development and maintenance of medical records and other necessary technologies are the business of a medical group, not its individual members. Investment in infrastructure that includes eHR and ePrescribing technology is no more remuneration to the individual physician members of that group than the development and maintenance of paper-based health record and prescription systems. Surely, a medical group decision to deploy technology **in its own business** does not create a financial relationship with physician group members. Is a compensation relationship exception needed to enable a medical group to furnish examination rooms or chairs in the waiting room? So long as any capital expenditure remains the property of the medical group, the expenditure does not create a financial relationship for purposes of Section 1877 of the Act.

2 The patient will also likely see other non-physician-providers such as a laboratory and one or more imaging centers, all of which could be unrelated to the hospital.

not otherwise have convenient access. To maximize the quality and efficiency of that patient's care, all providers will need access to the patient's complete medical record, which means the medical records of each and every provider involved in the diagnosis and treatment of the patient.

There is also no guarantee that any of the physicians, other than the surgeon and the anesthesiologist, will be members of the hospital's medical staff. While the hospital, the surgeon, and the anesthesiologist can take advantage of the exceptions in building and participating in an eHR network, the limitations in the proposed exceptions could exclude the other physicians involved in the patient's care, unless those physicians are willing to make the investment in necessary technology.

It is also common for primary-care groups to contract with specialists to treat their patients. To maximize the benefit of seamless migration of patients among the primary-care and specialist physicians, these physicians need to be on the same eHR network. As currently written, however, the proposed exceptions will not permit primary-care groups to donate technology to the specialists who treat their patients, because these specialists will not be members of the same group practice. Indeed, with the exception of multi-specialty medical groups, it is highly unlikely that the various physician providers involved in a patient's care will be sufficiently affiliated to use the exception to donate technology to each other to build an eHR network.

The only potential abuse from expanding the list of recipients of this technology is the fear that physicians will be tied to donating providers through eHR relationships. But as you acknowledge in the Preamble, interoperability largely eliminates this concern. Since the recipient can use the technology to share medical records with the donor's competitors, it is difficult to conceive how expanding the list of recipients increases the risk of fraud and abuse; a retailer who gives internet access to prospective customers is likely to find that internet access facilitates, not hinders, customer access to the retailer's competitors.

With fully interoperable systems, the donating entity would be no more guaranteed referrals as a result of the donated technology than entities that did not donate the equipment. In addition to interoperability, limiting potential recipients to physicians with whom the donor shares patients will also minimize this risk, because donor entities will be unable to use eHR technology to encourage referrals from random physicians. Also, perhaps the best deterrent is the potential expense associated with building an effective eHR network for the entity's patients. While it remains entirely unclear how expensive adopting a comprehensive eHR system will be, it is clear that the venture will be quite

expensive; not being able to guarantee these referrals due to the interoperability of the donated technology will sufficiently deter entities from engaging in widespread donations of this expensive technology.

Finally, we hope that excluding medical groups on the list of potential recipients was a mere oversight. Medical groups are separate legal entities from the physicians who own them and the physicians they employ. The provision of medical services and all that it entails is a medical group's business, not its member physicians'. To this end, it is the medical group that develops and maintains medical records and other necessary technologies for the operation of its business. Accordingly, if another entity donates ePrescribing or eHR technology to be used by group physicians, the appropriate recipient is the medical group, not the individual physician. It is important to note that it is unlikely that another exception will protect donations from hospitals and other DHS entities to physicians of medical groups with whom the DHS entity contracts. For instance, the fair market value requirement for the indirect compensation exception will not apply since the universal requirement that items and services be priced at fair market value could not be met where the items or service are donated. At the very least, forcing entities to rely on existing exceptions applicable to indirect relationships will create a chilling degree of uncertainty, hindering the spread of eHR technology.

Finally, it is difficult to conceive how donations of technology to be used in a medical practice can be made to physicians rather than their employers, the medical group. Even if the donations are made to individual physicians, the technology will inure to the benefit of and be used solely by the medical group that employs the physician.

Perhaps you chose to make the recipient the physician rather than his or her medical group because the proposed regulations limit recipients of hospital-donated technology to members of the hospital's medical staff. And perhaps you were concerned that unless all members of a certain medical group were also members of a hospital's medical staff, donating technology to the medical group, and thus presumably benefiting all group physicians, might induce other group physicians to switch their allegiances to the donating hospital. As is the case with most other fraud and abuse concerns, this concern should largely be eliminated where the technology is fully interoperable; it is highly doubtful that an entire medical group will change its referral patterns because it receives technology that will work just as well with medical record systems maintained by their current referral recipients.

For these reasons we urge you to expand the list of potential recipients to include physicians and medical groups who share patients with the donor regardless of the physicians' or medical groups' affiliation with the donor. We also strongly encourage you to include medical groups as potential recipients of technology from hospitals.

Expand the Definition of Covered Technology for eHR Exceptions

By limiting the permissible eHR technology to software and training only, the exceptions impede the ability of providers to adopt widespread eHR systems that provide maximum portability and efficiency. Many smaller medical groups and solo-practitioners, particularly those in rural areas, do not have the technology to implement eHR systems. Limiting donations to software and training will not spread eHR technology to physicians concerned about maintenance, technical support, connectivity, and the cost of ancillary hardware. Physicians will be as reluctant to pay for these needed items and services as they are to pay for the software and training entities would be permitted to donate under the proposed rule. Unless donor entities are allowed to donate all necessary technology to bring a physician (or their medical group) into an eHR network, the exceptions will not further the goal of widespread adoption of eHR systems, because it is highly unlikely that these physicians or their medical groups will make the necessary investment in hardware and other technology that will allow them to operate the donated software. Accordingly, we urge CMS to expand the definition of covered technology for the eHR exceptions to include the same technology permitted under the ePrescribing exception.

Because the eHR technology will be interoperable, the risk that donor entities will successfully use expensive hardware and other technology to induce referrals from recipients is minimal, even if the hardware or other technology can be used for purposes other than eHR transmission. So long as the donated technology can be used to link multiple providers, the donation of the technology should have minimal impact on the recipient's referral patterns.

In addition, any potential program abuse accompanying expanding covered technology to include all technology will be further minimized by the requirements that the technology be "necessary" for the implementation of the eHR technology. Because donations will be limited to only those items and services that physicians or their medical groups do not already have, risks that entities will use the technology to induce or reward referrals will also be minimal.

Selection of Recipients

To maximize the benefits of eHR and ePrescribing technology, recipients must necessarily be selected to expand the number of patients covered by the eHR and ePrescribing systems. CMS appears to acknowledge this in both the Preamble and in the text of the post-interoperability eHR exception by allowing entities to use volume metrics in selecting recipients so long as they are not directly based on the volume of business between the donor and the recipient.

eHR and ePrescribing systems will necessarily be built and tested in phases. For hospitals, this likely means that eHR systems will be rolled-out department by department. If eHR systems are to cover as many patients as possible, hospitals and other donors must have the flexibility, particularly during the initial stages, to select recipient-physicians from their busiest departments and with whom the donor shares the greatest number of patients. These criteria, however, will have the unintended and indirect result of leading donors to select recipients who do the most business with the donor.

The Preamble and text of the post-interoperability regulation suggest that donors may select recipients based on the total volume of all work performed by the recipient, such as the total number of prescriptions written by a particular physician annually. The Preamble also suggests that CMS will not, however, permit donors to select recipients based on the total number of patients that the donor and recipient share. This proposal stymies the development of widespread eHR and ePrescribing systems because hospitals will go the safer route of selecting high volume physicians with little patient overlap vs. lower volume physicians who share more patients with the donor. Such a result is inconsistent with the goal of maximizing efficiency and portability, and will only serve to impede the adoption of ePrescribing and eHR technology. In short, the proposal will tend to minimize the number of patients covered by the eHR network.

Like all other risks of program abuse associated with donations of eHR and ePrescribing systems, interoperability should minimize the concern that selecting recipients based on their practice volume will facilitate the use of eHR technologies to reward referrers.

We urge CMS to adopt final regulations that permit donors to select recipients of covered technology based on the number of patients the recipient and donor share. We also encourage CMS to permit hospitals to select recipients by hospital department, which include permitting hospitals to select recipients who share patients with the hospitals busiest and highest-volume departments.

Cap on Value of Donations

We urge you to abandon any attempt to place a cap on the value of the donated technology in the final regulations. As the Preamble appears to acknowledge and as is widely accepted, there is simply no way to reasonably predict the costs of implementing ePrescribing and eHR systems on the scale hoped for by Congress, the Department of Health and Human Services, and the health care community. Cost estimates for deploying eHR systems vary enormously. With such unstable estimates, it would be impossible to set any reasonable fixed-amount cap on the value of the technology, and we encourage you not to do so at this time.

Compounding this problem, various recipients will have varying needs to implement ePrescribing and eHR systems, with some requiring very little and others requiring significantly more. While this issue could be addressed by adopting a cap reflecting the highest possible cost per recipient, such an approach would require reliable data on these potential costs, which simply does not exist. If a fixed-amount cap reflects an average cost to all recipients, then those recipients with greater needs will be required to bear the costs of eHR and ePrescribing technology above the cap amount. A cap calculated as a percentage of the value of a particular donation will also require physicians to bear costs for systems not particularly valued by physicians. We are particularly concerned about any cost-shifting to physicians who are, as discussed above, already reluctant to transition their practices to ePrescribing and eHR systems. If the final regulations require that physicians bear even modest costs in addition to the other meaningful non-monetary burdens that implementing eHR and ePrescribing systems will require, the regulations will prove lethal to the widespread adoption of these important technologies.

In addition, a cap on the value of the donations will not be needed to minimize potential fraud and abuse if systems are interoperable. The Preamble explains that the purpose of the cap would be to minimize the influence the donated technology might have on physician referral patterns, particularly where a donor might try to hide remuneration to a referring physician in unnecessarily expensive and valuable technology. While this might be a concern if the technology were capable of tying a physician to a particular DHS entity, interoperable systems that allow physicians to use the technology with any provider should eliminate this concern. The physician gains no continuing benefit by referring to the entity that donated the technology, because it can use the technology with any other referral recipient.

We also fail to see how a no-cap system gives larger providers a competitive advantage over smaller providers because the larger providers are able to donate more or more valuable technology. Indeed, interoperability allows all providers to take as much advantage of the donated technology as the provider, large or small, who donated it.

Perhaps the cap is meant to ensure that donors do not reward historically higher-volume referrers with more valuable technology. But a cap is too blunt an instrument to address this concern. Rather, the other limitations in the exceptions, such as the requirements that the technology be necessary and that donations not be directly related to referrals, appear to adequately address this concern. It also seems that this concern is better addressed under the anti-kickback statute, because the Stark Law is ill-suited to address fraud and abuse concerns involving remunerating physicians for prior referrals. The anti-kickback statute is designed to punish entities for conduct motivated by forbidden intent. Contrariwise, the Stark Law looks only forward – its goal is to preempt potentially abusive arrangements by forbidding certain conduct regardless of the actors' intent. This is true even where, as with the deployment of eHR and ePrescribing technology, the result of the relationship is undeniably positive. Using the Stark Law to reach arrangements that are clearly beneficial to patients based on the potential for bad intent on the part of the actors will only needlessly stifle the development of these important technologies, particularly where the anti-kickback statute is available to address those proceeding with improper intent.

Finally, providers who will bear the financial burden of adopting ePrescribing and eHR technology will be doing so for the primary purpose of improving patient care. These providers, such as hospitals and large medical groups, will invest vast amounts of capital with very little in financial return. It would seem, then, that these providers' desire to minimize these costs through judicious, rather than wanton, donations of interoperable technology to other entities will also minimize the potential for fraud and abuse.

For these reasons, we strongly urge you to not include a cap on the value of the donated technologies in the final regulations. A cap is likely to transfer eHR costs to physicians, thus impeding the widespread adoption of these important technologies if they place even modest costs on physicians.

Definition of Electronic Health Record

It is unclear why CMS would need to further define the term "electronic health record" to minimize fraud and abuse theoretically associated with eHR system donations.

After all, electronic transmission of and access to patient records or other data such as clinical decision support does not constitute remuneration any more than access to paper-based patient records and clinical decision support data. That is, a donor entity sharing important clinical data about a patient, whatever their form, is not a "donation" of eHR or ePrescribing technology. Rather, it is sharing information about a patient, which should not be deemed remuneration or even remotely potentially abusive. Accordingly, it is unclear why CMS would seek to limit the data shared between health care providers in exceptions designed to define what technology can be donated between providers. Nonetheless, any definition of electronic health records should be very broad and include anything that is currently considered part of patient medical records. Any eHR exception should also include other clinical information technology, such as clinical decision support and computerized provider order entry (CPOE) systems. Clinical decision support data is critical to patient care, and most eHR systems provide clinical decision support. Efforts to minimize potential fraud and abuse should not include requiring donors to deny access to valuable clinical data related to patient care, even if access to such data might be helpful to physicians in their private practice.

Pre-interoperability / Post-interoperability

While we applaud the effort to provide protection to providers for potential violations of the Stark Law pending the adoption of the interoperable certification standards, it is unlikely that the extremely limited pre-interoperability exception will prove practically useful in the dissemination of eHR technology. It is doubtful that providers will make an enormous investment in eHR technology based on the rather unhelpful pre-interoperability exception, particularly if it is likely that the exception will sunset after the interoperability certification standards are finalized. Rather than encourage you to expand the pre-interoperability exception, we encourage you to adopt the certification standards for interoperability as soon as possible, and certainly no later than finalizing the post-interoperability exception.

Interoperability Certification Standards

We have no specific comments regarding which standards CMS should adopt to assure interoperability of eHR systems, though we do urge CMS to set realistic standards. Accordingly, we strongly encourage CMS to continue to work closely with the provider community in selecting the standards so that they reflect both patient needs and realities of the health care market place.

Expanding ePrescribing to Cover Orders Other Than Pharmacy

We encourage CMS to expand the ePrescribing exception to include all technology used to electronically transmit physician orders for all items and services that require a physician order, such as orders for laboratory and diagnostic imaging services. We can think of no increased risk of program abuse associated with expanding the breadth of the ePrescribing system to include these orders.

Donations of Use

We ask CMS to specify that technology donations covered by the exceptions include the donation of the right to use technology, so that DHS entities can clearly lease or license technology, rather than be required to transfer ownership of the donated technology. We are confident that this is CMS's intention, but suggest that the proposed exceptions could be revised for greater clarity on this point. We can think of no potential increase in risk of potential abuse by allowing donors to donate use of eHR or ePrescribing technology, as opposed to the technology itself.

Requiring Participation in eHR and ePrescribing Systems

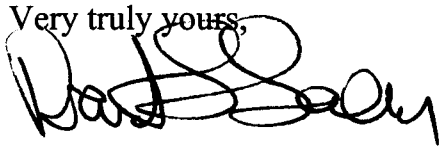
Currently, the regulations prohibit recipients from conditioning the receipt of technology on doing business with the owner. Please clarify that donors may require their recipients to participate in the donor's eHR and ePrescribing systems. That is, donors cannot require recipients to do business with the donor, but can require the recipients to use the donor's eHR and ePrescribing systems; hospitals and other entities will need the ability to insist that otherwise reluctant physicians use these technologies if they are to achieve widespread adoption of these electronic systems. We can think of no additional risk of abuse associated with hospitals and other entities requiring participation in eHR and ePrescribing systems, so long as donations are not conditioned, by either party, on doing business with the other.

Using eHR and ePrescribing Systems to Lure Physicians to the Donor Entity

CMS seems particularly concerned that donors will use the donated technology to lure patients away from competitors. Leaving aside whether any such campaign could be successful, interoperability should also minimize this risk; it is unclear how a hospital will lure a physician away from a competitor by giving the physician technology that can be used just as easily with the competitor. Nevertheless, the Preamble only obliquely describes the conduct this requirement forbids, and there is no corresponding provision in

the text of the regulation. Please clarify whether this prohibition simply states that the exceptions will not protect donations of items and services that are conditioned on the recipient doing a certain amount of business with the donor, or whether the relevant passage in the Preamble is intended to have other implications.

Very truly yours,



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EMO - lt2DHHS (01005-032) (9Dec05)

The Certification Commission
for Healthcare Information Technology

DEC 13 2005

December 8, 2005

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

(Submitted electronically via www.cms.hhs.gov/regulations/ecomments)

Comments on the Proposed Rule:
Medicare Program: Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements

*Comments on **Background** Section of document.*

CCHIT strongly supports the decision by CMS to simultaneously propose exceptions at §411.357(w) and §411.357(x) for electronic health records software and training services that are not covered by the MMA-mandated exception (page 10 of document).

We believe the MMA-mandated exception, standing alone, would have insufficient impact on health IT adoption or the quality and safety of care, for two reasons:

- First, while there is good evidence that the cost of hardware, software and training for electronic health record systems is a significant barrier to adoption by physicians, there is no such evidence that cost is the major barrier to standalone e-prescribing systems; in fact, free giveaways of e-prescribing systems by payers have demonstrated very low acceptance by physicians.

- The MMA-mandated exception requires that the e-prescribing hardware, software and training be used ***solely*** to receive and transmit electronic prescriptions. The exception does not require e-prescribing to include basic screening for drug interactions, contraindications, allergies, or dose correctness, and thus omits the tools needed to improve drug safety. In addition, as currently structured, the MMA-mandated exception would encourage greater fragmentation of electronic patient information rather than integration. Without tying in the patient's diagnoses, laboratory results, and other data, along with decision support tools to utilize this information for prescription checking, a standalone e-prescribing system provides only a small part of the potential available in an electronic health record, and would fail to achieve the full potential benefits to quality and safety.

Comments on "Exceptions for Certain Arrangements Involving Electronic Health Records Items and Services: §411.357(w) and §411.357(x) (page 33 of document)

CCHIT reiterates its support for including these exceptions to support the adoption of electronic health records (EHR). We believe there are clear circumstances in which a hospital, group practice, Medicare prescription drug plan, or Medicare Advantage plan can donate electronic health record technology to physicians, which could help accelerate the adoption of interoperable health IT and improve the quality and safety of care, without risk of program and patient abuse. We wish to add, however, that these exceptions alone will not suffice, and that widespread health IT adoption will require pay-for-performance incentives within the healthcare reimbursement system.

Comments on the concept of pre- and post-interoperability exceptions (page 34).

Since the rule proposes differing requirements for the period before and after the Secretary of HHS adopts product certification criteria, we would like to provide updated information on the timing and availability of product certification.

CCHIT is engaged in developing the Compliance Certification and Inspection Process for Electronic Health Records under HHS Contract #HHSP233200454102EC. Certifying EHR systems for ambulatory care – the domain of physician office practices, the target of the proposed exception – represents our first scope of work under that contract. The contract requires CCHIT to publish proposed certification criteria by December 30, 2005, and to complete a pilot test by February 28, 2006. CCHIT published its proposed criteria on November 30, 2005, one month ahead of contract deadline, and is on track for the timely completion of the pilot test as well. This should lead to inspection of ambulatory EHR systems beginning in March 2006, with official certification results available in June 2006. In addition, while the standards for ePrescribing are still being finalized, we anticipate beginning certification of ePrescribing within EHRs on September 30, 2006.

While we cannot predict the interval between CCHIT's deliverables and the Secretary's adoption of product certification criteria, we recommend CMS and OIG consider a scenario in which certification criteria are in place ***before*** the proposed rule takes effect, making the need for a "pre-interoperability" exception moot. This could simplify the process of formulating the EHR exception.

Comments on the risk of program abuse posed by a DHS entity's provision of valuable technology to physicians (page 34).

We do not agree with the statement, "The provision of electronic health records technology poses greater risk of abuse than the provision of limited electronic prescribing technology, because electronic health records technology is inherently more valuable to physicians in terms of actual cost, avoided overhead, and administrative expenses of an office practice." Although ultimately EHRs may increase the efficiency of an office, in the near term they are disruptive to workflow and frequently require additional staff rather than fewer. This is one reason why adoption has remained so low.

Instead, we believe the risks of program abuse should be separately analyzed for each of the elements in obtaining, implementing and supporting an EHR system. We would identify the following three elements and their risks:

- Computers and network equipment (i.e., "hardware") can be used for many purposes and has some resale value, although it depreciates rather rapidly. Therefore, we believe that donation of hardware may pose some risk of abuse.

- Donation of EHR software, training, and implementation assistance, in contrast, does not carry significant risk of patient or program abuse. These products and services can not serve other functions, and can not be resold by the practice or "taken back" by the donor. Converting an office from paper to electronic records by installing software, retraining staff, and re-engineering workflows is a labor-intensive and even painful process for the practice. We do not believe it could act as a "perk" to induce or reward a higher volume of referrals.

- Ongoing technical support, generally paid for on a monthly or annual basis, is a third essential element in obtaining and using EHR systems. CCHIT believes that donation of ongoing support could pose a risk of abuse for two reasons: it creates a dependency of the physician upon the donor – a 'crash' of an EHR system that was no longer supported would have a devastating effect on the practice -- and second, the fair market value of such support is very difficult to establish.

In summary, CCHIT believes that if the exception focuses on donation of EHR software, training, and implementation, the risk of program or patient abuse is negligible. We believe the risks are higher for donation of general purpose computing hardware as well as for long-term ongoing system support.

Comments on the value of protected technology (page 42)

CMS is contemplating placing a cap on the aggregate value of the technology donated. We share CMS' concerns about the risk of donating multifunctional, resalable hardware, but we reiterate our position about the low risk of abuse when software and training are donated.

As long as the donation is focused on software and training, we suggest that a cap in the value of donated technology could be counterproductive -- disadvantaging smaller offices and primary care practices most in need of help, and/or encouraging the adoption of less sophisticated EHR systems that do not fully achieve quality and safety improvement goals.

Estimates vary regarding the purchase cost of electronic health record systems, but the figures range from $15,000 to $35,000 or more per physician. As a rule of thumb, approximately 1/3 of the investment goes to hardware, 1/3 to software, and 1/3 to training and implementation consulting. Unfortunately, the small offices that represent the

slowest adopters of health IT experience the highest per-physician cost because of their inability to spread the cost among many providers. A fixed per-physician cap could increase rather than decrease that 'adoption gap.'

We also suggest CMS bear in mind that healthcare IT investment, as a percentage of revenues, is small compared to other industries. Hospitals spend 4-5%, and physician offices less than 1% of revenues, while other knowledge-driven industries invest 10% or more in IT. When payment systems are realigned to reward quality, the appropriate amount of health IT investment could be several times higher than it is now. Besides limiting total provider investment in health IT, an exemption with a fixed cap might inhibit capital investment in health IT research and development.

Comments on requiring that electronic health records include a CPOE component (page 49)

Computerized Provider Order Entry (CPOE) is a functionality within electronic health record systems. Prescriptions are the most frequent "order" entered in the physician offices, and this functionality has been covered by the e-prescribing requirements. However, advanced EHRs with full CPOE can also accept orders directed to laboratories, imaging centers, medical equipment suppliers, physical therapists, and other ancillary service providers. The practicality and availability of CPOE in ambulatory EHRs will evolve over time, and CCHIT's certification criteria will require increasing levels of full CPOE capability as it becomes feasible. Instead of touching upon this specific functionality in the proposed rule, we believe decisions on the appropriate timing and depth of CPOE functionality required in a physician office EHR is best left to the deliberations of the certifying body.

Thank you for this opportunity to comment.

Respectfully submitted,

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