CMS-1303-P-26 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Ms. Janet Dillione **Date & Time:** 12/12/2005

Organization : Siemens Medical Solutions Health Services

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See attachment

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

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

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

CMS-1303-P-27 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

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

Organization : Florida Hospital Association

Category : Health Care Provider/Association

Issue Areas/Comments

Issue

Background

Providing an exception to the Stark rules for e-prescribing and electronic health records will accelerate physician use of health information technology.

Provisions of the Proposed Rule

The proposed rules provide an exception for stand-alone e-prescribing systems. However, limiting the exception to e-prescribing alone is much too restrictive. Hospitals and physicians need to exchange clinical information across the full spectrum of patient care and e-prescribing should be an integrated component of the complete electronic health record. This would allow the sharing of diagnostic information, test results, and treatments among those involved in the patient's care. The covered technology noted in the proposed rule is too narrow and does not appear to allow for the integration of administrative functions within the clinical electronic health record. We question if the stand-alone devices referenced in the proposed rule are even available in the market and if a physician would want to use such restrictive devices.

In addition, requiring that such devices be necessary and not duplicative of any other technology items or services that the physician might have puts a significant burden on the hospital to certify what items and services the physician has and that they are not in any way duplicative. Knowing what is meant by "technically or functionally equivalent" is also of concern and needs more guidance as to how this should be determined and by whom.

CMS-1303-P-28 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Mr. Ken Whittemore Jr. **Date & Time:** 12/12/2005

Organization : SureScripts, LLC

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Our full comments are contained in our attachment.

CMS-1303-P-28-Attach-1.DOC

SureScripts
The prescription for better healthcare™

December 12, 2005

Submitted electronically via
http://www.cms.hhs.gov/regulations/ecomments

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

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

Dear Sir/Madam:

This letter is in response to the Proposed Rule that the Centers for Medicare and Medicaid Services ("CMS") published in the Federal Register, Volume 70, Number 195, beginning on page 59182, on October 11, 2005. SureScripts appreciates the opportunity to comment on these proposed rules that propose to create an exception to the physician self-referral prohibition in Section 1877 of the Social Security Act for certain arrangements in which a physician receives necessary non-monetary remuneration that is used solely to receive and transmit electronic prescription drug information.

INTRODUCTION AND BACKGROUND

SureScripts was founded in August, 2001, by the National Association of Chain Drug Stores ("NACDS") and the National Community Pharmacists Association ("NCPA"), which together represent the interests of the 55,000 chain and independent pharmacies throughout the United States. SureScripts is committed to building relationships within the healthcare community and working collaboratively with key industry stakeholders and organizations to improve the safety, efficiency, and quality of healthcare by improving the overall prescribing process. At the core of this improvement effort is SureScripts Electronic Prescribing Network, a healthcare infrastructure that establishes electronic communications between pharmacists and physicians and enables the two-way electronic exchange of prescription information. You and your staff can find more information about SureScripts at www.surescripts.com.

The SureScripts Electronic Prescribing Network is the largest network to link electronic communications between pharmacies and physicians, allowing the electronic exchange of prescription information. SureScripts has signed agreements with, and tested and certified the software of, pharmacies and pharmacy technology vendors representing more than 85 percent of U.S. pharmacies. In addition, SureScripts has signed contracts with 50 physician technology companies who supply electronic health record and electronic prescribing applications to over 150,000 current physician users. Physicians are expressing a stronger interest in electronic prescribing as they become increasingly aware of the known efficiencies and safety factors, as well as the emphasis placed on the process by the Medicare and Medicaid programs.

SureScripts does not develop, sell or endorse specific electronic prescribing software. Instead, SureScripts works with software companies that supply electronic health record (EHR) and electronic prescribing applications to physician practices and pharmacy technology vendors to connect their solutions to the SureScripts Electronic Prescribing Network.

Technology vendors cannot connect to the SureScripts Electronic Prescribing Network until they complete a comprehensive certification process. As part of its certification process, SureScripts establishes ground rules that safeguard the fairness of the prescribing process, including rules that, among other things, serve to protect patient choice of pharmacy and physician choice of therapy. On a technical level, the certification process specifies the standard technical format for transmitting prescription information and tests each vendor's electronic connections to the network.

The certification rules also serve to ensure that prescribing decisions are based on best medical practices, and are not influenced by improper financial considerations or the interests of one particular entity over another. For instance, by prohibiting inappropriate commercial messaging to physicians at the point of prescribing, SureScripts is helping to safeguard the fairness of the process.

As the largest electronic prescribing network, we are very supportive of the benefits that can be achieved in improving health quality, reducing prescription errors, and lowering costs through the broad adoption and effective implementation of electronic prescribing and electronic health care technologies nationwide. The implementation of these technologies requires a capital commitment on the part of pharmacies and physicians. Physicians in particular might not always be in a position to devote the capital resources necessary to implement the necessary technological infrastructure to permit electronic prescribing. We believe, however, that there are a number of stakeholders that have an interest in promoting electronic prescribing and the safety and efficiencies that come with it, and such stakeholders are willing to fund the technology necessary to promote electronic prescribing. Accordingly, we wholly support CMS's attempts to provide a clear framework in which the stakeholders with the financial resources to promote the electronic prescribing infrastructure may donate hardware, software, training, and other services

in order to foster and promote implementation of electronic prescribing and electronic recordkeeping.

SureScripts was founded on the premise that physicians and patients should have complete freedom of choice, without undue influence, to select the pharmacies and drug protocols of their choice. In that same vein, SureScripts supports the purpose of the Self-Referral Law prohibiting a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship.

THE PROPOSED RULE

1. Electronic Prescribing Exception: §411.357(v)

A. "Necessary" Items

CMS has proposed an exception for the provision of items and services that are "necessary and used solely" to receive and transmit electronic prescription drug information. SureScripts supports CMS's broad interpretation of "necessary" to include hardware, software, broadband or wireless internet connectivity, training, information technology support services, and other items and services (for purposes of this letter, we will refer to all such items and services collectively as "Items") used in connection with the transmission or receipt of electronic prescribing information. We strongly encourage that CMS not place any limitations on the types of Items that a Donor can provide to a Recipient, so long as they are necessary to conduct electronic prescribing. We strongly urge CMS to not limit the concept of "necessary" to the minimum necessary to conduct electronic prescribing. Different software and hardware that would be subject to donation may have different degrees and types of functionality, and one could argue that the elements in a system with a higher functionality may not be absolutely necessary for electronic prescribing, but are nonetheless used for that purpose and often enhance clinical practices and safety. For example, the only drug information that is *necessary* to accomplish electronic prescribing is a simple list of drug names, strengths, and dosage forms. However, the provision of complete drug monographs in electronic prescribing applications gives prescribers valuable information at the point of care that can improve patient outcomes—a highly desirable situation. Thus, we would not want CMS to create a situation where donations can only be made of the hardware, software, or services that are the minimum necessary to conduct electronic prescribing. Donors should have the option of donating systems that are advanced and state-of-the-art for purposes of promoting electronic prescribing.

B. Technological and Functional Equivalence

CMS has stated that the exception would not protect arrangements in which a Donor provides Items that are "technically or functionally equivalent" to Items the Recipient currently possesses or has obtained. In the commentary, CMS has used examples describing the necessary

differences as having to be "material" or "significant." We are concerned that the commentary will create a materiality standard for the differences in technology or functionality that was not intended by Congress. We also are concerned that the lack of specificity or objective standard with respect to what would constitute a difference in technology or functionality. Moreover, if a materiality standard is adopted, we are concerned that the lack of a definition of "material" or "substantial" will create confusion and will act as a deterrent to Donors providing Items. We are also concerned that a Recipient will not have the technical expertise, and in fact believe that it is likely that a Recipient will not have the technical expertise, to determine whether the Items being donated are "technically or functionally equivalent" to Items the Recipient currently possesses or has obtained. We strongly encourage CMS to promote the donation of Items by clearly stating that any change or difference in technological or functional capabilities will make an Item not technically or functionally equivalent to another.

CMS proposes to require recipients to certify that the items and services to be provided are not technically or functionally equivalent to items or services the recipient already possesses or has obtained. CMS has not stated, however, who is to determine whether an Item is technically or functionally equivalent to an Item the Recipient already has. As stated above, SureScripts is concerned that Recipients will not have the technical capability or sophistication to understand fully the technological and functional attributes of either the systems that they have and that they are proposing to receive from a Donor, and that Recipients are not in a position to execute such a certification with any degree of certitude. Minor enhancements may appear material to the technologically unsophisticated. Because, as stated above, we are concerned that questions will arise as to whether a service is technically or functionally equivalent, we believe that this proposes a significant barrier to the donation of Items, and strongly urge that CMS reconsider, or clarify, its position on this matter. In specific, we would recommend that the an exception apply so long as the Recipient certifies in good faith, and without fraudulent intent, without investigation, that the donated Items are not technically or functionally equivalent to existing Items.

C. Items Used "Solely" For Prescribing.

SureScripts understands that Congress directed CMS to adopt an exception for items used "solely" for the transmission or receipt of electronic prescribing information, and that CMS intends to strictly construe Congress' mandate regarding solely. While we are aware that there are stand-alone applications used solely for electronic prescribing, most systems are multi-functional and it is clearly the intent of Congress and the industry to promote multi-functional devices capable of not only sending and receiving electronic prescriptions, but also for an electronic health record. We believe that the use solely limitation will result in very few donations. It is clearly far more cost-effective, and in line with the business strategies of the Donors and Recipients, to use items that are multi-functional. SureScripts is encouraged by CMS's statement that it intends to use its independent rule-making authority to issue additional exceptions, so long as a "substantial use" of the items or services is to receive or transmit

electronic prescription information. While we fully support the issuance of additional exceptions, we are concerned that any limitations to "a substantial use" to electronic prescribing will still create an insurmountable barrier to the donation of items. The reality is that electronic prescribing may not be a substantial use of even a multi-functional device. While SureScripts understands that CMS would not want to encourage or condone the donation of systems not related to electronic prescribing or an electronic health record, such as systems that would permit, by way of example, personal e-mailing, contact management and calendaring, we strongly encourage CMS to adopt an exception that would protect the donation of equipment used for electronic prescribing and other functionality directly related to an electronic health record, without attempting to quantify the amount of use dedicated to a particular functionality. Such an approach would be consistent with the President's mandate that all persons have an electronic health record by 2014.

2. Inappropriate Commercial Messaging.

In enacting the Medicare Modernization Act, Congress was concerned with the potential threat that the abuse of electronic prescribing technology might pose to patient and physician autonomy. In particular, the MMA requires that electronic prescribing standards "allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems to reduce medication errors, avoid adverse drug interactions, and improve medication use." See 42 U.S.C. § 1395w-104(e)(3)(D). Similarly, the MMA Conference Report states that, under electronic prescribing, physicians should have access to "neutral and unbiased information on the full range of covered outpatient drugs," and that Congress did not intend for e-prescribing "to be used as a marketing platform or other mechanism to unduly influence the clinical decisions of physicians." H.R. Conf. Rep. No. 108-391, at 455-56. CMS also noted in the recently promulgated Final Rule on electronic prescribing standards that it has "concerns about how the provision of certain information [through e-prescribing] may unduly influence physician prescribing patterns." 70 Fed. Reg. 67,568, 67,583 (Nov. 7, 2005). CMS stated in the Final Rule that inappropriate messages include those that would steer the filling of a prescription to a particular mail order pharmacy, and electronic "detailing" messages from a manufacturer promoting a particular brand or brand-name drug.

SureScripts is acutely aware of the strong desire and intent that some entities, including but not limited to technology vendors, manufacturers, payers, pharmacy benefit managers (PBMs), pharmacies, laboratory service providers, and others in the clinical technology space have to inappropriately influence physicians' choice of medication therapy and patient's choice of pharmacy for Medicare beneficiaries. Inappropriate and misleading messages could be and, in some cases, are planned to be delivered with the intent to influence a physician's choice of therapy and/or a patient's choice of pharmacy by entities who financially or strategically gain from the message delivery, physician's decision of therapy, or patient's choice of pharmacy. Some plans are to (1) disguise this message as a "clinical alert" based upon biased research not published in the public domain nor sourced at the time of message delivery or (2) the alert would

be positioned as saving a patient money when further investigation would prove the selection of pharmacy in fact costs the patient additional moneys in out-of-pocket costs. There is little question that these and other entities will engage in this inappropriate messaging unless CMS creates clear, specific, and unequivocal rules prohibiting such activities within the practice of electronic prescribing.

As stated above, SureScripts' certification rules serve to ensure that prescribing decisions are based on best medical practices, and are not influenced by improper financial considerations or the interests of one particular entity over another. While the SureScripts certification rules are designed to prohibit the very inappropriate commercial messages cited by CMS and Congress as being problematic, we nonetheless strongly urge CMS to incorporate into its final exception on electronic prescribing strong and specific prohibitions against the types of inappropriate messaging that are discussed in this response. Software systems that allow inappropriate commercial messaging or hinder physician or patient choice should not be eligible for antikickback exceptions.

Sample rules related to inappropriate messaging are attached hereto as possible model language for consideration by CMS. These guidelines have been developed and modified over the last two to three years by SureScripts, and have been agreed to by many technology vendors and multiple other stakeholders including health systems, pharmacies, physician groups, pharmaceutical manufacturers, and payers. We believe these messaging guidelines could serve as the foundation of policies related to inappropriate messaging. Doing any less will permit an environment of abuses to evolve that will surely impede the rapid adoption of electronic prescribing and electronic health records that was contemplated by Congress.

3. Additional Conditions on the Provision of Qualifying Electronic Prescribing Technology.

A. Value of Protected Technology.

CMS is considering limiting the aggregate value of the qualifying electronic prescribing technology that a Donor could provide to a Recipient under the exception. SureScripts does not support a limit on the value of Items that a donor could provide. First, given the realistic nature of the types of items that would be donated, we think it unlikely that any cap is necessary. Second, we believe that any cap would be difficult to ascertain in a systematic manner, consistent with respect to all recipients and donors. Third, given the uncertainty on how to value an item, we believe that a cap would only further discourage donors and recipients from availing themselves of the exception.

In the event that CMS were to adopt a cap, we support the approach of measuring the monetary limit at fair market value to the recipient (i.e., the retail value). We agree that this approach would be consistent with the anti-kickback statute's intent requirement, and would

minimize any competitor's disadvantage for smaller entities that do not have financial resources or the buying power of larger organizations.

SureScripts does not support setting an initial cap, which would be lowered after a certain period of time. First, donors should be encouraged to donate items to recipients as they enter into the marketplace (i.e., new physicians) or who might not be earlier adopters of electronic prescribing. Second, as technologies advance, donors should not be discouraged from providing to recipients state-of-the-art technology and enhancements to existing technology.

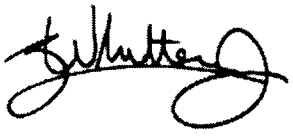
4. Pre-Emption of State Law.

While not specifically addressed in the proposed rule, SureScripts strongly encourages CMS to adopt rules that would pre-empt state laws that would pose barriers to the donation of items as permitted by the exception. As you know, the foundation regulations contained broad pre-emption language pre-empting state laws that would prohibit electronic prescribing. We strongly encourage the pre-emption of state laws that would impede the donation of items otherwise permissible under federal law.

CONCLUSION

SureScripts appreciates the opportunity to continue to provide advice and assistance to CMS as it works to adopt an exception for electronic prescribing. We hope CMS will continue to take advantage of the experience that SureScripts can share with respect to the real-world implementation of electronic prescribing for the purposes of improving the safety, efficiency, and quality of the overall prescribing process. Please do not hesitate to have your staff contact us should they have any questions regarding the comments we have offered above or if the are any other ways that we can assist them in this important work.

Sincerely,



Ken Whittemore, Jr.
VP, Professional and Regulatory Affairs

ken.whittemore@surescripts.com
(703) 921-2114

Attachment

SureScripts Recommended Rules to Prohibit Inappropriate Messaging in Electronic Prescribing Systems and Transactions

(a) *General.* Part D sponsors and their subcontractors, pharmaceutical manufacturers, pharmacies, and vendors of e-prescribing technology shall neither permit nor engage in inappropriate messaging in the establishment, maintenance, and operation of e-prescribing technology or an electronic prescription drug program.

(b) *Penalties.* Violations of this section shall be subject to Intermediate Sanctions as described in section 423.750.

c) Definitions and Guidelines

1. *Definitions*
   a. "Prescribing decision" means a physician's decision to prescribe a certain Part D drug or direct the patient to a certain pharmacy.
   b. Point of care refers to the time, commencing upon the physician's review of a patient's medical record and terminating upon the physician's signature on the prescription, during which a physician or his/her agent is engaged in the act of prescribing a Part D drug for a patient.
2. Except as specified paragraphs (4) and (5), Technology Vendors shall not use, alter, or modify their systems in any manner that would direct, influence, or encourage a physician or patient, at the point of care, to prescribe, select, or use a specific Part D drug or pharmacy, as compared to other Part D drugs or pharmacies.
3. Technology Vendors shall not use any means, program, or device, or knowingly permit any other person to use any means, program, or device, including, but not limited to, advertising, instant messaging, and interruptive messaging (e.g., "pop up" ads), to direct, influence or attempt to direct or influence, through economic incentives or otherwise, the prescribing decision of a physician at the point of care, or to make more difficult or unduly burden a physician's or patient's selection of a particular pharmacy or Part D drug as compared to another pharmacy or Part D drug if such means, program, or device (as described above) is triggered by, initiated by, or in specific response to, the input, selection, and/or act of a physician or his/her agent prescribing a Part D drug or selecting a pharmacy for a patient
4. Notwithstanding the above, Technology Vendors may display or present information regarding a Part D plan's formulary and benefit design, including lower cost Part D drug and pharmacy options, the tier placement of Part D drugs, prior authorization, step therapy, coverage status, and co-payment information, even if such information influences the patient or physician's choice of pharmacy or other prescribing decisions, so long as (i) such display or presentation is neutral and unbiased and the source of the information is identified, (ii) the End User may access all Part D drugs known through generally available sources used in the industry, and all pharmacies including all retail and mail service pharmacy options available, and (ii) nothing is designed to preclude a physician or patient from selecting any particular pharmacy or Part D drug.
5. Additionally, any lists created and maintained by End Users within a Technology Vendor's software product including, but not limited to, (i) an individual End User's list

of most frequently prescribed Part D drugs, (ii) an individual End User's list of most frequently used pharmacies, (iii) an individual End User's most frequently used SIGs (i.e., instructions for the use of medications), would not be considered a violation of this Section.

CMS-1303-P-30 **Physicians Referrals to Health Care Entities With Which They Have Financial Relationships- E-Prescribing Exception**

Submitter : Mr. Thomas Smith **Date & Time:** 12/12/2005

Organization : Evanston Northwestern Healthcare

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1303-P-30-Attach-1.DOC

EVANSTON NORTHWESTERN HEALTHCARE

Information Systems

1301 Central Street, Evanston Illinois 60201
(847) 570-5421 fax (847) 492-9245

December 13, 2005

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

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

On behalf of Evanston Northwestern Healthcare, we endorse the comments to the proposed regulation in question as submitted by The National Alliance for Health Information Technology. The recommendations made in the Alliance comment letter submitted to CMS dated December 8, 2005, reflect a consensus view in the healthcare field that the regulation as written will not achieve the intended effect of promoting the widespread adoption of health information technology and its productive use by America's physicians.

The Alliance's comments knowledgeably explain the impact and likely reception to the proposed regulation by the physician community and by those hospital organizations that are capable and willing to support the desire of physicians to provide better, safer and more efficient care for their patients. Remedies to the unintended inhibiting effects of the proposal regulation are necessary; these changes are important to the interests of both the healthcare industry and the Department of Health and Human Services in accelerating the acceptance of information technology and the interoperable exchange of patients' medical information among health care providers.

Health care IT offers the potential to dramatically reduce medical errors and enhance the efficiency of medical care by providing clinical support at the point of care in physician offices and hospitals. The potential savings are tremendous in both human lives and Medicare resources. But this promise can only be achieved if physicians participate fully and continually in the public-private sector campaign to provide the means for employing interoperable electronic health records. We appeal to CMS to reconsider its proposed regulation and strike a balance in the Stark law that truly advances this national goal

Sincerely,

Jeffrey H. Hillebrand
Chief Operating Officer

Thomas W. Smith
Chief Information Officer

Submitter : Mr. Brian Vandenberg
Organization : Allscripts Healthcare Solutions
Category : Health Care Industry

Date: 12/12/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Issue

Background

No comments

Collection of Information Requirements

No comments

Provisions of the Proposed Rule

See attachment

Regulatory Impact

No comments

Submitter : Mr. Thomas Wilder

Date: 12/12/2005

Organization : America's Health Insurance Plans

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1303-P-32-Attach-1.DOC

America's Health Insurance Plans

601 Pennsylvania Avenue, NW
South Building
Suite Five Hundred
Washington, DC 20004

202.778.3200
www.ahip.org

December 12, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1303-P
7500 Security Boulevard
Baltimore, MD 21244-8010

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

Dear Sir/Madam:

America's Health Insurance Plans (AHIP) is writing to provide comments regarding the Proposed Rule published by the Centers for Medicare & Medicaid Services (CMS) in the *Federal Register* on October 11, 2005 concerning certain exceptions to the physician self-referral prohibition contained in Section 1877 of the Social Security Act. The exceptions permit hospitals, group practices, Medicare Advantage (MA) organizations, and Medicare Prescription Drug Program (PDP) sponsors to provide certain items and services to physicians for electronic prescribing and electronic health records (EHRs). The exceptions in the Proposed Rule are based, in part, on provisions contained in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (PL 108-173).

AHIP is the national association representing nearly 1,300 member companies providing health insurance coverage to more than 200 million Americans. Our member companies offer medical expense insurance, long-term care insurance, disability income insurance, dental insurance, supplemental insurance, stop-loss insurance, and reinsurance to consumers, employers, and public purchasers. AHIP and its member health insurance plans support the development of a national health information infrastructure that improves health outcomes and care delivery. Many AHIP members (including member health insurance plans that are MA organizations and PDP sponsors) are using health information technology (IT) to add value to health care services and empower consumers and their caregivers through access to information and decision support tools.

AHIP believes the Proposed Rule generally strikes an appropriate balance between the needs of physicians who may need assistance to develop health IT systems and the underlying purpose of

federal fraud and abuse laws to promote the professional independence of the physicians receiving such support. As discussed below, we have several comments and recommendations for modifications to the Proposed Rule that we believe will strengthen the Final Rule when it is issued.

I. Electronic Prescribing Exception

a. "Necessary" Non-Monetary Remuneration

The Proposed Rule (42 CFR §411.357(v)) limits the permitted support to items and services, "necessary and used solely to transmit and receive electronic prescription drug information . . . ." This requirement of the Proposed Rule, which adopts the MMA language allowing an exception from the fraud and abuse laws for electronic prescribing support, ensures that the items or services will be used to encourage electronic prescribing activities. We believe, however, that the section could be further strengthened by requiring that the items or services be clearly intended to promote the interoperability of health information and the improvement of quality in a clinical setting. Adding this requirement will make clear that the items or services support the overall goals of the national health information infrastructure by demonstrably improving the quality of care received by consumers.

Recommendation:

AHIP recommends adding an additional requirement to section 411.357(v) as follows:

> The items or services are clearly intended to promote the interoperability of health information and the improvement of quality in a clinical setting.

b. Definition of "Interoperability"

The preamble to the Proposed Rule notes that CMS is considering adopting a definition of "interoperability" which would be defined as "the ability of different information systems, software applications, and networks to communicate and exchange information in an accurate, secure, effective, useful, and consistent manner." (70 Fed. Reg. 59186). The definition is based on an interoperability definition contained in 44 USC §3601(6). We believe this definition accurately captures the requirements of an interoperable health IT system and should therefore be included in the Proposed Rule. We agree with the addition in the proposed interoperability definition of the word "secure" because we believe security requirements are a key component of any system that is used for the sharing of confidential health information.

Recommendation:

AHIP recommends that the following definition be added to the Final Rule when it is issued:

> As used in this section the term "interoperability" shall 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.

c. Prohibiting Restrictions on the Use of Items or Services

The Proposed Rule requires that the entity providing the items or services may not limit or unnecessarily restrict the use or compatibility of the items or services with other electronic prescription information items or services or electronic health information systems. In addition, the items or services must be available to all patients of the physician who receives the permitted support. We support these criteria in the Proposed Rule because they make clear that the items or services must promote the interoperability of health information systems and may not operate in a way that restricts patient care.

d. Value of Protected Technology

The preamble to the proposed rule requests public comment on the appropriateness of imposing a cap on the fair market value of items or services provided to a physician from a single donor. AHIP shares CMS' concern that allowing donors to provide items or services without limiting the value of such support could provide a potential for fraud and abuse. However, we believe the criteria in the Proposed Rule -- along with the additional requirements that we have recommended that the items or services are clearly intended to promote the interoperability of health information and the improvement of quality in a clinical setting -- will provide adequate safeguards.

It may be difficult to quantify the "reasonable" value of some items given the rapid changes being made in health IT systems and the services needed to implement and support such systems. In addition, it may be administratively burdensome for donors and recipients to calculate with any certainty the value of multi-functional IT systems as well as any necessary future enhancements. For these reasons, AHIP believes that the Final Rule should not specify a monetary cap on the value of items and services.

e. Written Arrangements

The Proposed Rule (42 CFR §411.357 (v)(7)) requires the entity providing items and services and the recipient to memorialize their agreement. The agreement must be signed by the parties, specify the items or services that are being donated, and contain a certification by the physician that the items and services are not technically or functionally equivalent to items and services he or she already possesses or has obtained.

AHIP believes written documentation is appropriate because it can clarify how the permitted support will be used to promote interoperable health IT systems and improvements in care delivery. The agreement also shows that the support is not intended to compromise the professional independence of the physicians who are recipients of the items or services.

We believe that the agreement should include a certification covering all of the criteria for the provision of items and services set out in the Proposed Rule for electronic prescribing. The

certification will demonstrate that the parties have carefully considered the regulatory requirements in their decision to provide and receive covered items and services.

Recommendation:

AHIP recommends that the agreement required by the Proposed Rule include the following additional certifications:

- That the items and services are donated as part of, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are furnished.

- That the entities will not take any actions to limit or restrict unnecessarily the use or compatibility of the items or services with other electronic prescription information items or services or electronic health information systems.

- That the items or services are of the type that can be used for any patient without regard to payor status and that the donor will not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

- That neither the eligibility of a physician for the items or services, nor the amount or nature of the items and services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

II. Electronic Health Record Exceptions

AHIP supports the provision of the Proposed Rule that allow an exception for Electronic Health Record (EHR) software or training services that are provided to physicians so long as the an electronic prescribing component is included. To the extent that we have suggested modifications to the Proposed Rule with respect to electronic prescribing items or services, AHIP believes these recommendations should also be included in the EHR requirements.

In addition, we believe the distinction made in the Proposed Rule between "pre-certification" and "post-certification" EHR discourages the adoption of interoperable health information systems. The preamble to the Proposed Rule allows an exception for "pre-certification" EHR software or training services because "there are no proposed Federal regulatory standards for electronic health records, nor are there any product certification criteria with which electronic health records software can comply." (70 Fed. Reg. 59188)

In fact, the Certification Commission for Health Information Technology (CCHIT) has been working over the past year to develop certification requirements for an ambulatory electronic health record. The CCHIT has broad representation from health care providers, health insurance plans, and health IT vendors and the group was recently awarded a contract by the Department of Health and Human Services to develop certification criteria for EHRs. We understand that CCHIT intends to have its first round of product certification available by March 2006.

Because CCHIT is actively working on a certification specification for electronic health records, we see not need for the Proposed Rule to include a "pre-certification" EHR exception. Instead, we suggest that 42 CFR §411.357(w) of the Proposed Rule (electronic health records items and services that are not certified) be deleted and that the Secretary recognize CCHIT as the certification standard for electronic records. In addition, any items or services should comply with applicable interoperability standards once they are developed.

Recommendation:

AHIP recommends that CMS require that EHR software that is the subject of the exception in the Proposed Rule meet certification standards established by the Certification Commission for Health Information Technology. At such time as interoperability standards are developed, the EHR software should meet those standards if such software is to qualify for the exception.

III. Additional Issues

At the federal level, many efforts are underway to formally create a national health information infrastructure. Although some electronic health processes currently exist in limited forums, it is not yet known how the national infrastructure will develop or evolve. For these reasons, CMS should continuously evaluate its regulatory requirements to ensure that they do not have a negative impact on development of future health IT initiatives.

The Proposed Rules do not contain any provisions which would enable CMS to evaluate and ensure that the regulatory requirements, once enacted, have not negatively impacted key stakeholders or business segments within the health care industry (e.g., payers, vendors, providers). CMS should conduct a study to ensure that: (1) the professional independence of the entities receiving the support has been compromised; (2) the impact, if any, on the quality of care received by consumers; and (3) whether the permitted support has promoted the electronic exchange of health information and the use of information technology to improve quality in a clinical setting.

AHIP and its member health insurance plans recognize the improvements in health care that can be achieved through the application of health information technology such as electronic prescribing and electronic health records. Our members have committed resources to integrate health IT into their business operations and have extended support to the provider community to assist with their adoption of information technology systems. We believe the Proposed Rule establishes a reasonable and narrowly-tailored exception to the physician self-referral prohibitions in the Social Security Act that will allow further support for physicians while continuing the important protections of the federal fraud and abuse requirements.

Sincerely,

Thomas J. Wilder
Vice President, Private Market Regulation

Submitter : **Mr. Ronald Woessner** **Date: 12/12/2005**

Organization : **Zix Corporation**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Issue

Provisions of the Proposed Rule

Please see attached comment to proposed 42 CFR 411.357(v)

CMS-1303-P-33-Attach-1.DOC

zixcorp

December 12, 2005

Hon. Mark B. McClellan, M.D., 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: Proposed Exceptions for Electronic Prescribing Arrangements (File Code CMS-1303-P)

Dear Dr. McClellan:

Zix Corporation applauds CMS for recognizing EPrescribing technology as viable, beneficial service for the health care community and supports the efforts of the Department of Health and Human Services to establish standards and policies for industry activity. We appreciate the opportunity to comment on the proposed rule[1] ("**Proposed Rule**") creating an exception to the prohibition on physicians' referrals to health care entities with which they have financial relationships for certain electronic prescribing arrangements, to be codified at 42 C.F.R. § 411.357(v).

Zix Corporation is the parent company of PocketScript, Inc. ("**PocketScript**"), a leading vendor for EPrescribing and prescription management services. The PocketScript application currently is certified by RxHub and SureScripts, and PocketScript is the EPrescribing vendor for the country's largest EPrescribing initiative in Massachusetts. In 2005, over 1 million electronic prescriptions have been sent through this Massachusetts EPrescribing initiative. In addition to allowing providers to write and transmit prescriptions electronically, PocketScript's services enable providers to have point-of-care access to real-time drug formularies and comprehensive drug data. Physicians prescribing drugs are prompted to prescribe safe and cost-effective drugs. Providers can view patient drug histories for all past prescriptions to ensure that prescriptions are being filled and no therapies are being duplicated. The comprehensive drug

[1] Centers for Medicare and Medicaid Services, Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements; Proposed Rule, 70 Fed. Reg. 59182 (Oct. 11, 2005).

reference guide offered by PocketScript provides detailed information on every drug available to providers.

As an entity that serves as a trusted hub of connectivity for predominantly health care industry clients, Zix Corporation appreciates the effort that CMS has put into crafting an exception for EPrescribing arrangements, as required by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "**MMA**"). We are mindful of the challenges of crafting an exception that can be implemented in a workable manner with regard to a rapidly expanding, technologically-dependent field. Nonetheless, Zix Corporation believes that specific improvements can be made to the proposed exception that will enhance its practical value in the final rule. Zix Corporation's position in the health care marketplace provides a close affiliation with many of the stakeholders who will be affected by the Proposed Rules. These stakeholders include those most directly affected by the Proposed Rule - payors, pharmacy benefit managers, hospital associations, and physicians and medical office staff. Our comments are based on the real world experience of working with millions of users from these classes of health industry stakeholders who rely on the SysTrust-certified data center that we maintain for our EPrescribing and secure electronic messaging applications. We believe that adopting our suggested revisions will result in a final rule that fosters widespread adoption of EPrescribing and contributes to significant cost savings and reduction of medical errors, while continuing to protect the Medicare and Medicaid programs against risk of abuse in the way that Congress intended when enacting the MMA.

Electronic Prescribing Exception: § 411.357(v)

Structural Comment

Zix Corporation believes that, as presently drafted, the proposed exception places an unreasonable degree of risk on DHS entities that sponsor programs to distribute free electronic prescription technology. Specifically, the proposed exception's requirements that a device actually be used[2] and also "used solely"[3] in connection with an approved electronic prescription program place a DHS entity sponsor at significant risk of

[2] Proposed 42 C.F.R. § 411.357(v)(2), 70 Fed. Reg. at 59197.

[3] Proposed 42 C.F.R § 411.357(v).

violation in the event a physician engages in conduct beyond the sponsor's control, such as using the device for a purpose other than electronic prescribing or failing to use the device at all. DHS entities sponsoring deployment of electronic prescribing technology have no way of monitoring or precluding use of devices and connectivity for multiple purposes because vendors that provide the hardware cannot control the use of the devices outside of the EPrescribing context. As a result, a sponsor may bill for DHS provided as a result of a referral from a physician who uses a device for clinical purposes that are complimentary to, or perhaps even unrelated to electronic prescriptions. For example, use of a device to run software made available under the proposed exceptions at 411.357(w) or 411.357(x), each of which requires that electronic medical records software include electronic prescribing functionality, is one use of the device that appears not to be subject to exception under the present proposed rules. Zix Corporation believes this is a structural flaw in the proposed rules and urges CMS to revise its approach to the "used solely" requirement, and to exercise its discretion to adopt an exception for multiple-use devices and connectivity in the manner more particularly described below.

"Used Solely"

The proposed exception reflects the requirement of the MMA that the items and services provided to the physician be "used solely" for the transmission or receipt of electronic prescribing information.

Response: As interpreted by CMS in the preamble to the proposed rule,[4] this requirement makes the exception of little practical value and is entirely at odds with the underlying purpose of the MMA in requiring the establishment of the exception, *i.e.*, the expansion of electronic prescribing. We encourage CMS to consider that electronic prescribing occurs most frequently in a clinical context where a physician must access and create information about the patient to make a diagnosis and prescription in accordance with the appropriate standard of care. It is unrealistic to think that a physician would utilize one computer or handheld to perform some aspects of patient care and an entirely separate device to generate the electronic prescription information. Zix believes that a more realistic approach would be to provide that a device or connectivity will be deemed to be "used solely" for the transmission or

[4] 70 Fed. Reg. at 59185.

receipt of electronic prescribing information if it (a) is used in connection with the receipt or transmission of electronic prescription information conforming to the then current standards under Medicare Part D; and (b) also is used for one or more of the following complimentary purposes:

1. Creating clinical documentation (*e.g.*, dictation, treatment notes)[5]
2. Accessing patient documentation or test results[6]
3. Clinical decision support (*i.e.*, reviewing online medical references, accessing clinical guidelines, reviewing the medical literature, responding to automated alerts and reminders)[7]
4. Obtaining information from payers for treatment coverage and co-payment amounts for medical services or determining whether a specific service has been pre-authorized
5. Capturing encounter data for claims purposes[8]
6. Reviewing patient schedule[9]
7. Accessing/updating on-line medication administration records[10]
8. Voice or text-based electronic communication with the patient, other clinicians, providers or payors (*i.e.*, using the handheld device to call or email someone)

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[5] A physician could use a software application to assemble a note or dictate a note to an audio file for immediate or later transmission to an electronic medical record or transcription service offered by a third party application service provider.

[6] Software provided by a third-party application service provider would enable display of medical test results on a hand-held device, either through independent connectivity or through interface with a hospital's medical record.

[7] Software on the hand-held device would enable the physician to access content supplied by a third-party provider, using connectivity that may be provided by yet another service provider.

[8] Physician enters requisite coding information to initiate billing for each patient encounter using a software application on the hand-held device. Information is transmitted directly to a local server and, from there, to a server hosted by a third-party application service provider. The application service provider then formats the information into a bill, which is then sent to the patient or payor.

[9] Using software on the hand-held device, the physician looks up a schedule for the date of the proposed appointment.

[10] Using software on the handheld device the physician documents that specific therapeutic medications have been administered to the patient. This information may then be transmitted to support claims generation or to become part of the patient's medical record.

We believe the above-described approach to the "used solely" requirement enhances the utility of the proposed exceptions by enabling physicians to use devices received under the exception to realize efficiencies in clinical practice.

Performance of some or all of the above-referenced complimentary activities would be enhanced through bundling of software functionalities in the device itself. While we understand CMS's concerns about the potential for abusive arrangements relating to bundled software, we do not believe that the value of the additional software functionality creates an incentive of sufficient magnitude to lead to abuse. We note that CMS has proposed exceptions for electronic medical records technology[11] that mandate incorporation of EPrescribing functionality to facilitate the goals of the MMA. We believe our approach to the "used solely" requirement similarly would enhance access to electronic prescribing technology by permitting incorporation of other functionality necessary to medical decision making that is of lesser value than the electronic medical records functionality excepted by the proposed exceptions in proposed 411.357(w) and (x).

At a minimum, we believe that any resolution of CMS's concerns in this regard must take into account the realities about the clinical context in which electronic prescribing occurs, and the types of information that a physician must have available to function appropriately in that context. We believe that such a solution should encompass software that provides functionality for one or more of the above-referenced complimentary purposes. CMS's proposal to provide separate treatment for devices and connectivity would not address this practical consideration in the context of clinical decision making. By way of example of the approach we suggest, CMS might elect to specify the types of functionality for software that may not be made available under the exception, rather than creating a sweeping prohibition against any bundling of software in a way that does not meet the exigencies of clinical practice.

We note that our approach also can be harmonized with CMS's approach to the prohibition in the current proposed exception that would prevent a physician from accepting duplicative technology, such as an additional handheld device limited to EPrescribing if he or she already has a handheld device that could perform such functionality if it had the

[11] Proposed 42. C.F.R. §§ 411.357(w), (x), 70 Fed. Reg. at 59197.

appropriate software drivers and applications. Specifically, in our view a device pre-loaded with bundled software that integrates electronic prescribing technology with software to support any of the above-referenced complimentary activities would be an upgrade that "significantly enhance[s] the functionality of the item or service" and therefore within the scope of permitted donations under the existing exception.[12]

Additional Exception for Multi-Functional Hardware and Connectivity Services

CMS proposed using its regulatory authority to create an additional exception for the provision by DHS entities to physicians of hardware (including necessary operating system software) and connectivity services that are used for more than one function, so long as a "substantial use" of the item or service is to receive or transmit electronic prescription information.[13]

Response: Regardless of whether CMS elects to modify its approach to the "used solely" requirement, Zix Corporation believes that it is imperative that CMS exercise its discretionary authority to create an exception for the provision of multi-functional hardware or connectivity services. If CMS maintains a restrictive interpretation of the "used solely" requirement, the additional exception for e-prescribing devices and connectivity is the only exception that will have practical value, since most physicians will choose to use hardware with multi-functional capabilities. As noted above, an exception for multiple uses also would be required in order to use the hardware or connectivity services made available under 411.357(v) to run the software made available under 411.357(w) and (x), and to provide protection for DHS entities that sponsor deployment of electronic prescribing technology against potential violations arising from use by physicians of the device or connectivity for unapproved purposes. For these reasons alone, CMS should strongly consider adopting a multi-use exception.

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[12] 70 Fed. Reg. at 59185.

[13] *Id.*

Definition of Substantial Use

The preamble to the proposed rule provides that the proposed exception for multi-functional hardware and connectivity services would be limited to situations where EPrescribing was a "substantial use" of the device or connectivity being provided.[14] CMS is soliciting public comment regarding an appropriate definition of "substantial use" in the context of electronic prescribing technology and its use.

Response: Zix Corporation proposes that, in the event CMS elects to limit a multi-function use exception to devices and connectivity for which electronic prescribing is a "substantial use", the term "substantial use" should be defined as follows:

> "For purposes of this paragraph, 'Substantial Use' means that the device is to be used to transmit or receive information in connection with electronic prescribing conforming to the then current standards under Medicare Part D; and one or more of the following activities:
> - Creating clinical documentation (*e.g.*, dictation, treatment notes);
> - Accessing patient documentation or test result;
> - Clinical decision support (*e.g.*, reviewing online medical references, accessing clinical guidelines, reviewing the medical literature, responding to automated alerts and reminders);
> - Obtaining information from payors;
> - Capturing encounter data for claims purposes;
> - Reviewing patient schedule;
> - Accessing/updating on-line medication administration records;
> - Voice or text-based electronic communication with the patient, other clinicians, providers or payors; or
> - Similar uses relating to patient treatment."

Capping the Value of Protected Technology

In the preamble to the proposed rule, CMS indicates that it is considering (a) whether to impose a cap on the value of hardware or services that could be supplied legitimately under the proposed exception for multi-

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[14] *Id.*

functional devices and connectivity services;[15] and (b) whether to limit the aggregate fair market value of all items and services provided to a physician from a single donor.[16] CMS has solicited public comment with regard to (1) the nature and amount of any cap that should be imposed on the value of donated multi-functional hardware or connectivity services; (2) the amount of any aggregate cap; (3) the methodology used to determine an aggregate cap; (4) whether the same cap would be adequate if there were protection for the donation of multi-functional hardware and connectivity services; (5) whether the cap should be reduced over time; and (6) whether the cap places a disadvantage on smaller entities that do not have the financial resources of larger chains or organizations.

Response: Zix Corporation opposes the proposed caps. Zix Corporation believes that is would be premature to impose a cap at this time as the technology is highly diversified and the market not yet mature. Until there is a realistic way to assess the typical value of sponsored technology and services, we believe CMS should not impose a cap on the value of hardware or services that could be supplied under any or all of the proposed exceptions. Specifically, we believe a cap to be ill-advised for the following reasons:

(a) There is insufficient data about a typical suite of technology that would facilitate expanded use of electronic prescribing to serve as a basis for a decision about where to draw the line between an appropriate donation and a donation that risks creating undue potential for program abuse from referrals in exchange for the donation;

(b) History shows that the market will independently regulate pricing for computing technology and connectivity services to reduce the cost of technology over time in connection with the ongoing pace of technological advancement;

(c) Electronic prescribing software and services, devices and connectivity likely will be provided by independent vendors who will not necessarily be aware of the value of the items or services provided by the others;

(d) The value of the technology to be provided under the exceptions is not so substantial that it is likely to influence physician behavior;[17]

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[15] 70 Fed. Reg. at 59185.

[16] 70 Fed. Reg. at 59186.

[17] For example, the present market value of electronic prescribing services to an

(e) Requiring physicians to pay for components of service above a cap would substantially reduce the potential for diffusion of the technology;
(f) Developments in pricing, payment modality, and market delivery for electronic prescribing services and equipment (described in more detail below) are difficult to predict and a cap identified without clearer understanding of these areas could prove unduly constraining.

Zix Corporation believes that under these circumstances, imposing a cap would frustrate not further the goals of the MMA by placing artificial limits on the potential value of technology and services available to be included in programs without a clear sense of what is needed to achieve the goal of increasing use of electronic prescribing.

In the event that CMS elects to impose a cap notwithstanding the above-described objections, Zix Corporation strongly opposes adoption of a fixed dollar amount, such as the $300 limit on non-monetary compensation reflected in 42 C.F.R § 411.357(k). To be effective, a cap on the value of donated electronic prescription technology cannot approach the potential donation from the perspective of a one-time purchase. Rather, any cap would need to be flexible enough to address variations and developments in pricing, payment modality, and market delivery, and likely would need to cover a span of several years or renew on an annual basis. In our view, the most sensible way to determine any cap would be to align its structure with the realities of the costs and fee structure of hardware, software and/or services that it would cover. Of particular importance in this regard are the following:

1. License fees: Connectivity services and access to hosted[18] software applications usually are priced on a subscription basis, subject to an annual or monthly fee.

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individual physician amounts to less than one percent (1%) of the median gross income for primary care physicians in 2003. *See* Medical Group Management Association, 2004 Physician Compensation and Production Survey (describing median 2003 compensation for primary care physicians as $156,902).

[18] With respect to EPrescription software, a "hosted" application is one where the first full data record representing the electronic prescription is built off-site, using centralized equipment owned, run, and located at an entity other that the provider (*i.e.*, a clearinghouse) and the first electronic transmission of the electronic prescription is from that entity. A non-hosted application involves initial construction and electronic transmission of the data record representing the electronic prescription on equipment at

2. Training fees: Training is a normal component of a package relating to licensing of hosted software; however, it often is priced separately from the principal software license and may include per diem or reimbursement components that could change over time.
3. Support and maintenance fees: Support and maintenance often is purchased separately from the license to hosted or non-hosted software, connectivity services, or equipment. Pricing can vary dramatically, depending on the type and nature of the support and maintenance service involved
4. Initial device costs: Due to the short retail life cycle of a microcomputer, pricing for devices with comparable functionality can vary widely depending on how long the particular device has been on the market. Nonetheless, a device that has been on the market longer and has a correspondingly lower market value may require more frequent upgrades (*e.g.*, operating system, memory) to perform properly as software develops. Upgrades often are made available to existing users free or for at substantial reductions from retail costs.
5. Device (non-OS) upgrades: Upgrading an old device to a newer model to integrate better with a new version of the hosted software.
6. The rapid pace of technological change in this area, particularly if upgrades and enhancements would be considered to be "new" (*i.e.*, non-duplicative) donations.
7. Renewability: license fees often renew on a periodic basis, sometimes at lower levels than the initial license.
8. Changes in Payment Methodology. Shifts in payment methodology from a guaranteed fixed fee per physician user to a combined subscription and performance component.

CMS's preamble to the final rule establishing E-Prescribing standards[19] provides further support for range of potential value associated with sponsorship of electronic prescribing programs. For example, there appears to be broad agreement that minimum EPrescribing start up costs for each physician in terms of hardware and software is approximately $1,500.[20] Such costs do not include connectivity, license fees, or support and maintenance which are reported at $1690 per year in one case and

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the provider's site.

[19] Centers for Medicare and Medicaid Services, Medicare Program, E-Prescribing and Prescription Drug Program (Final Rule), 70 Fed. Reg. 67568 (Nov. 7, 2005).

[20] 70 Fed. Reg. at 67587-88.

between $80 and $400 per month in other cases.[21] Where implementation costs can reach and exceed $4,300 per physician for EPrescribing systems alone,[22] when such systems are bundled with other functionality, it is no surprise that costs for an electronic health record with integrated EPrescribing functionality could exceed $9,000 per physician.[23] Zix Corporation believes that the substantial range of value of an EPrescribing program depending upon how many of the technology components and services it includes precludes imposition of a meaningful fixed dollar amount cap. In our view, a scalable cap that can accommodate the potential for variation among components of EPrescribing programs is the only effective way to implement a cap consistent with the MMA's goal of promoting adoption and deployment of EPrescribing technology.

In light of the foregoing considerations, Zix Corporation urges CMS to approach its decision regarding restrictions on the value of donated technology with the same degree of flexibility and pragmatism it employed in providing for profit-sharing and productivity bonuses under the group practice exception set forth at 42 C.F.R. § 411.352(i)(2). Specifically, CMS provided physician practice groups with multiple options for structuring physician compensation that balanced productivity incentives with concerns about potential program abuse. CMS could achieve the same balance between productive innovation and program protection by taking multiple approaches to donations. Such approaches might include limitations on donations covering a multi-year period that takes into account the value of both the hardware product, as well as the service subscription and software support and maintenance fees that likely will recur on an annual basis. Other options include looking for ways to value the service other than the fees paid by the donor, in order to take into account the potential for risk-sharing mechanisms to develop within the industry that enable third-party service providers to reap additional economic benefits from effective services in ways that may not change the

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[21] *Id.* at 67589.

[22] *Id.* at 67588.

[23] Highmark, Inc. a Pennsylvania licensee of the Blue Cross Blue Shield Association, has contributed $26.5 Million to fund a program administered by the Pittsburgh Foundation that will pay up to 75% of the cost for a physician's office to acquire, install and implement an electronic technology system up to a maximum of $7,000 per physician. *See Highmark, Inc. Contributes $26.5 Million to Fund Organization that Encourages Adoption of Health Information Technology*, (Nov. 15, 2005), available at https://www.highmarkehealth.org/images/E-Prescribing_110905.pdf (visited Dec. 9, 2005).

value of the core service to the physician. For example, a service provided might charge a sponsor a lower basic service subscription in exchange for the opportunity to share in savings that accrue from increased formulary compliance or prescription of generics. In this type of situation, focusing simply on either the subscription fee or the aggregate payment from the donor would misstate the value of the service.

Although Zix Corporation believes the best course of action would be to avoid a cap entirely, a suite of restrictions that provide the above-described kind of flexibility could provide an effective balance of encouraging increased adoption of electronic prescribing and protecting federal health program integrity.

42 C.F.R. § 411.357(v)(2)

Subsection 2 of the proposed exception requires that the items and services provided to the physician be part of, or used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the same are furnished.

Response: As noted at the outset of this comment, Zix Corporation is concerned that, as presently drafted, this requirement creates the potential for a Stark violation by an entity that bills for DHS provided as a result of a referral by a physician who obtains electronic prescribing technology donated by the DHS entity, but who fails to utilize it. While Zix Corporation appreciates the need to ensure that the benefits and efficiencies of electronic prescribing technology redound to the Medicare program, we believe it is inappropriate to penalize donors for recipients' failure to use a device or other technology. We are particularly concerned that maintaining the existing language will cause donors to require vendors such as Zix Corporation to engage in onerous monitoring and reporting obligations relating to individual physician use of donated technology. Such obligations could divert resources and significantly increase the costs and reduce the efficiency of electronic prescription services without materially enhancing the benefits to be realized from the service provided. We believe that a rephrasing of 411.357(v)(2) in the manner set forth below would address CMS's legitimate concerns in the area without the above-described undesirable consequences:

"(2) The items and services are donated as part of, or for use in connection with an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are furnished, and the contract with the physician provides that the donor may redeploy the device or service to another physician if the receiving physician fails to write a specific number of prescriptions using the service within a certain period of time."

Other DHS Entities.

CMS has solicited comment on whether it should use its discretionary authority to establish protections for electronic prescription technology and services provided to physicians by DHS entities other than those described specifically in the MMA.[24]

Response: Zix Corporation encourages CMS to use its discretionary authority to protect donations of electronic prescription technology and services to physicians by the following types of entities: Health care delivery systems, pharmacy distribution channels, including retail and mail order pharmacies, pharmacy benefit managers and insurance companies, and suppliers of prescribable non-drug items and services. We believe that, to the extent these entities do not directly provide DHS, they may, by virtue of their relationship to PDP sponsors, create the potential for indirect compensation arrangements between DHS providers and physicians unless an exception applies. We believe that these entities are equally or more likely to be interested in fostering the diffusion of electronic prescribing technology than those entities specifically listed in the statute. Our support for expanding the scope of the exception to include prescriptions for non-drug items and services (discussed at p. 12 below) also motivates us to advocate inclusion of suppliers of such services among those entities able to benefit from the protection of the exception.

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[24] 70 Fed. Reg. at 59186.

"Interoperability"

CMS has indicated that is considering imposing an "interoperability" requirement, such that the DHS entity (and agents thereof) offering the technology to the physician would be prohibited from taking any actions to disable or limit the compatibility interoperability of the technology with other information products.[25] CMS is considering defining 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." CMS is soliciting public comment regarding this requirement, its definition of "interoperable," alternative means of ensuring the maximum level of interoperability, and the types of software currently available for electronic prescribing.

Response: Zix Corporation supports the concept of interoperability to the extent that it means establishment of standards that foster communication among and between separate proprietary platforms. We would oppose a definition of "interoperability" that required Zix Corporation to accept and support transmissions from devices supplied by other vendors, or to require us to make our hosted applications accessible by software in other vendor's devices.

In connection with to the actual development of standards for interoperability, Zix Corporation also strongly supports implementation of a mandatory compliance regime that would include (a) a compliance deadline; (b) transition rules; and (c) enforcement authority and penalties for noncompliance. Providers of EPrescribing services must interface with a variety of entities, including switching companies, prescription benefits managers and health care clearinghouses, each of which addresses different aspects of the transmission and processing of electronic prescriptions and claims. Accommodating different platforms and standards maintained by each such entity is costly. An interoperability requirement that clearly establishing a compliance date, transition rules and penalties for noncompliance offers the best possibility for effectively managing costs associated with transition to the new standards and minimizes the potential for unpredictable cost increases were business partners of EPrescribing companies to transition their systems on different timetables.

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[25] *Id.*

Use of Electronic Prescribing Technology for Non-Drug Items and Services

CMS requested comment on whether the exception should permit qualifying electronic prescribing technology to be used for the transmission of prescription information regarding items and services that are not drugs, *e.g.* supplies or laboratory tests.[26]

Response: Zix Corporation urges CMS to expand the exception to cover physician orders for the widest possible range of items and services. Many items and services that are not drugs currently are "prescribed" using a prescription pad. The same advantages to be gained through electronic prescribing of drugs can be gained through electronic orders for other items and services. In addition, if CMS fails to include non-drug items and services within the scope of the exception, EPrescribing companies will be required to establish separate workflows for drug prescriptions and non-drug prescriptions. Zix Corporation believes that requiring separate workflows would be impractical and would have a chilling effect on the adoption of EPrescribing technology.

42 C.F.R. § 411.357(v)(6)

Subsection (6) of the proposed exception requires that neither the eligibility of a physician for the items or services, nor the amount or nature of items and services, be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

Response: As presently drafted, this requirement appears inconsistent with the purpose of encouraging broader use and adoption of EPrescribing technology, as well as some of the practical realities of the marketplace. A health plan sponsor of an electronic prescription program has a legitimate need to take into account the anticipated amount of use a particular physician will make of an electronic prescription service in deciding whether (a) it makes sense to facilitate the physician's access to the technology in the first place; and (b) to continue to make the electronic

[26] 70 Fed. Reg. at 59186.

prescription service available in situations where the service is provided on a subscription basis. While we appreciate CMS's desire to reduce the potential that an entity will provide access to EPrescribing technology and services on a quid pro quo basis rather than for sound business reasons, we believe that appropriate exceptions must be made to accommodate those aspects of program sponsorship that have a legitimate business purposes and that likely will not lead to abuse. The following example illustrates what we believe to be legitimate, nonabusive use of prescription volume information by a health plan sponsor in assessing eligibility for physician participation in an electronic prescription program:

> A health plan sponsor of an EPrescribing promotion seeks to realize cost savings from the deployment of the e-prescribing item or service by enhancing formulary compliance, reducing claims processing costs, and reducing costs by encouraging prescription of generic or multi-brand drugs. Under these circumstances, the sponsor obtains the greatest value from its investment in the EPrescribing technology if that technology is deployed to physicians who write large numbers of (paper) prescriptions. The only source of data regarding prescriptions that will be available to the health plan sponsor to assess potential recipients of EPrescribing technology will be the prescriptions written for individuals covered by that health plan. In the most likely scenario, the health plan would use its data to identify potential candidates for an EPrescribing promotion and provide contact information for those physicians to a third party vendor of electronic prescription technology or services, who would then contract with the physicians to provide the items or services that will be paid for by the program sponsor. Electronic prescription services often are charged on a subscription basis involving a flat fee for a period of service, regardless of the number of transactions. Such fees will enable health plans to effectively manage their investment in the EPrescribing program but, because the costs are fixed, a sponsor of an arrangement structured in this way will want to ensure that the physicians actually use the technology. Accordingly, volume of prescriptions processed electronically is the most effective measure for use of the service, but once again, the sponsoring plan will only have access to data relating to its covered individuals.

In light of the above example, we recommend that CMS revise proposed 42 C.F.R. § 411.357(v)(6) to provide that a determination will be deemed not to relate to the volume or value of referrals or other business generated between the physician and the DHS entity if it meets one of the following criteria:

> "(i) The determination is based on whether the recipient's total number of prescriptions (or electronic prescriptions) written for individuals covered by a health plan sponsor of an electronic prescription program exceeds a specific threshold that is set in advance;
>
> (ii) The determination is based on the total number of prescriptions (or electronic prescriptions) written by the recipient;
>
> (iii) The determination is based on the total number of the recipient's patients who are covered by the health plan sponsor of an electronic prescription program
>
> (iv) The determination is based on the recipient's overall use of computer technology in his or her medical practice;
>
> (v) The determination is based on whether the recipient is a member of the medical staff of a hospital, if the hospital is the donor; or
>
> (vi) The determination is based on whether the recipient is a member of the medical staff of a hospital that serves a significant number of patients who are covered by the donor, if the donor is a health plan."

Zix Corporation believes that our position on this issue is consistent with CMS's approach to encouraging broad dissemination and adoption of approved electronic medical records software. CMS's proposed approach to such software appears to reflect some understanding of the legitimate uses of information about prescription volumes. For example, proposed 42 C.F.R. § 411.357(x)(4) provides that a determination will be deemed not to relate to the volume or value of referrals or other business generated between the physician and the DHS entity if the determination is based on (a) the total number of prescriptions written by the physician; (b) size of medical practice or (c) overall use of automated technology within the medical practice.[27] We believe that CMS may have overlooked the fact that such information likely will only be available through self-reporting by the recipient and will not be independently verifiable.

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[27] 70 Fed. Reg. at 59198.

Obtaining the information required by CMS under section (x)(4) could add significant administrative costs and burdens that may discourage potential sponsors from donating technology. By contrast, the information described in the additional criteria proposed by Zix Corporation in the language above (items (i), (iii), and (vi)) is readily available to and independently verifiable by a potential health plan sponsor. Zix Corporation urges CMS to adopt this concept in the final electronic prescribing exception, and that it broaden the scope of the exception to better suit the electronic prescription context by including information available to a health plan sponsor by adopting the language suggested above.

42 C.F.R. § 411.357(v)(7) ("Written Agreement")

Subsection (7) of the proposed exception provides for a written agreement between the DHS entity and the physician.

Response: As presently drafted, this requirement is not consistent with existing reality in the implementation of device and connectivity programs. Agreements for hardware, training support, and, in some cases, wireless connectivity services are made between the physician and the electronic services provider, such as Zix Corporation's subsidiary, PocketScript. The donor DHS entity and the electronic services provider (*e.g.*, PocketScript) will have a separate agreement, under which the donor pays PocketScript to deploy the electronic prescription technology and services to an identifed group of physicians. Requiring an agreement between the DHS entity and the physician would insert the donor into the transaction between the physician and services provider. Requiring the health plan or other sponsor to be part of this contracting relationship would cause significant inefficiency, delay, and increased paperwork relating to the transaction.

Zix Corporation is concerned that, if implemented, this requirement will reduce the ability of potential sponsors who are not able to support the additional contracting volume to make available EPrescribing technology and services. At a minimum the requirement will significantly increase the time and process necessary to implement a program. These requirements could impose significant burdens that ultimately could cause breakdowns in the implementation of the program or substantially increase the time and cost associated with deployment. We believe such a result

would be contrary to the purposes for which the exception was required to be promulgated under the MMA. Zix Corporation urges CMS to revise the written agreement requirement to permit the required "agreement" between physician and donor to be accomplished indirectly, through a combination of agreements among the physician, third-party technology or service provider, and donor.

42 C.F.R. §411.357(v)(7)(iv) ("Technical and Functional Equivalence")

Paragraph (iv) of subsection (7) of the proposed exception requires that the written agreement contain a certification by the physician that the items and services are not technically or functionally equivalent to items and services he or she already possesses or has obtained. In the preamble to the Proposed Rule, CMS states that "the provision of a second hand-held device would not qualify for the exception if the physician already possesses a hand-held device that could run the [electronic prescription] software."[28]

Response: Zix Corporation believes that with respect to hand-held devices, a device should not be viewed as technically or functionally equivalent to one that a physician already possesses if the existing technology did not have electronic prescribing capability. We appreciate CMS's clarification in the preamble that handheld and desktop computers are not technically or functionally equivalent; however, we are concerned that preventing physicians who have an existing handheld device from obtaining a donated device with EPrescribing functionality will place substantial limits on the diffusion of electronic prescription technology. Zix Corporation believes that a new hand-held device that includes electronic prescription software is an upgrade of equipment that "significantly enhance[s] the functionality of the item" and should not be considered technically or functionally equivalent.

Our view is based on the dynamics of fulfilling orders in the mobile technology industry. Specifically, like most similar operations, PocketScript is organized to provide new subscribers with new handheld devices to write electronic prescriptions that have our proprietary EPrescribing application pre-installed. The installation is performed in a mechanized fashion as part of the technology deployment process in our

[28] 70 Fed. Reg. at 59184–85.

offices or a contracted fulfillment center. We do not have the service and support force to install the software on existing devices and, even if we were to establish such a force, it would substantially increase the cost of service without adding additional value to either the sponsor or physician. Most importantly, due to the difficulty of scheduling physicians' time, the distribution of new, pre-installed devices would remain the most effective means of obtaining the technology. CMS's current interpretation of technical and functional equivalence also would preclude a vendor from deploying a device to a physician who had EPrescribing service from a competitor. We believe that approach presents a significant barrier to competition and will stifle innovation in the electronic prescribing field by tying physicians to their existing service providers.

For the foregoing reasons, Zix Corporation believes that the certification requirement is inappropriate in the context of the mobile technology fulfillment industry and should be eliminated from the exception. In the event that CMS decides to retain the certification requirement, Zix Corporation believes that, at a minimum, the requirement should be revised to focus on devices or connectivity that are used for electronic prescribing. We believe that if CMS revises its approach to the definition of "used solely" to incorporate the activities described beginning on page 3 of this comment letter, it would be appropriate to preclude replacement of devices that can be used for that suite of activity. As noted above with respect to the written agreement requirement, Zix Corporation also believes CMS should revise the certification requirement to permit the certification to be included in the agreement between the physician and the technology or service provider, and to mandate that the DHS entity require the technology or service provider to obtain the certification in the overarching contract governing the program as a whole.

Costs of obtaining EPrescribing technology

CMS also sought comment on the retail and non-retail costs of obtaining electronic prescribing technology and the degree to which physicians may already possess items or services that could be used for electronic prescribing so as to be fully informed on this matter.[29]

[29] 70 Fed. Reg. at 59186.

Response: Zix Corporation is able to provide the following data and information to assist CMS with respect to understanding the current financial realities in the electronic prescription arena. The costs of providing electronic prescription services can be divided into the following several categories:

1. Cost of the hardware device
2. Cost of recruiting the physician
3. Installation of software on the hardware
4. Deployment/fulfillment process, including
    a. site survey to confirm IT infrastructure, and nature and extent of wireless and Internet access
    b. installation
5. User training (*i.e.*, physician and staff)
6. On-going technical support and system monitoring
7. Software licensing
8. Corporate overhead
9. Software development man-hours required to implement feature and functionality upgrades, requirements, and enhancements mandated by changes in regulations, business partners, or program sponsors.

Of these categories, only the cost of the hardware device currently has an established market price. Further, increased penetration of the technology will result in decreases in the cost over time. Unfortunately, due in part to the regulatory restrictions on various types of arrangements, it is not possible currently to predict the rate of adoption of electronic prescription programs in any meaningful way.

Electronic prescription services is a developing market and the data presently available is of scant predictive value because expectations regarding pricing and payment practices likely will evolve significantly over a short period. For example, we anticipate that there will be shifts in payment methodology from a guaranteed fixed fee per physician user to a "pay for performance" component that seeks to share savings accrued from increased formulary compliance or prescription of generics in exchange for a lower basic service subscription. We also anticipate that there will be shifts in method of delivering the sponsored technology or services to the market, including bundling of services with electronic medical records in the manner encouraged by proposed Section 411.357(w) and (x). These types of changes in payment modalities market

delivery method are characteristic of the development of other disruptive interventions in the prescription benefits industry, most notably with respect to prescription benefits managers and mail order pharmacies, and we expect them to apply in the electronic prescription context as well.

We hope CMS finds this information useful. For further information or if we may offer additional assistance, please contact the undersigned at 214.370.2219.

Respectfully submitted,

ZIX CORPORATION

Ronald A. Woessner
Senior Vice President and General Counsel

Submitter : **Mr. Carl Faulstick** **Date: 12/12/2005**

Organization : **Affiliated Healthcare Systems**

Category : **Laboratory Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attchment

zixcorp

December 12, 2005

Hon. Mark B. McClellan, M.D., 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: Proposed Exceptions for Electronic Prescribing Arrangements (File Code CMS-1303-P)

Dear Dr. McClellan:

Zix Corporation applauds CMS for recognizing EPrescribing technology as viable, beneficial service for the health care community and supports the efforts of the Department of Health and Human Services to establish standards and policies for industry activity. We appreciate the opportunity to comment on the proposed rule[1] ("**Proposed Rule**") creating an exception to the prohibition on physicians' referrals to health care entities with which they have financial relationships for certain electronic prescribing arrangements, to be codified at 42 C.F.R. § 411.357(v).

Zix Corporation is the parent company of PocketScript, Inc. ("**PocketScript**"), a leading vendor for EPrescribing and prescription management services. The PocketScript application currently is certified by RxHub and SureScripts, and PocketScript is the EPrescribing vendor for the country's largest EPrescribing initiative in Massachusetts. In 2005, over 1 million electronic prescriptions have been sent through this Massachusetts EPrescribing initiative. In addition to allowing providers to write and transmit prescriptions electronically, PocketScript's services enable providers to have point-of-care access to real-time drug formularies and comprehensive drug data. Physicians prescribing drugs are prompted to prescribe safe and cost-effective drugs. Providers can view patient drug histories for all past prescriptions to ensure that prescriptions are being filled and no therapies are being duplicated. The comprehensive drug

[1] Centers for Medicare and Medicaid Services, Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements; Proposed Rule, 70 Fed. Reg. 59182 (Oct. 11, 2005).

reference guide offered by PocketScript provides detailed information on every drug available to providers.

As an entity that serves as a trusted hub of connectivity for predominantly health care industry clients, Zix Corporation appreciates the effort that CMS has put into crafting an exception for EPrescribing arrangements, as required by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "**MMA**"). We are mindful of the challenges of crafting an exception that can be implemented in a workable manner with regard to a rapidly expanding, technologically-dependent field. Nonetheless, Zix Corporation believes that specific improvements can be made to the proposed exception that will enhance its practical value in the final rule. Zix Corporation's position in the health care marketplace provides a close affiliation with many of the stakeholders who will be affected by the Proposed Rules. These stakeholders include those most directly affected by the Proposed Rule - payors, pharmacy benefit managers, hospital associations, and physicians and medical office staff. Our comments are based on the real world experience of working with millions of users from these classes of health industry stakeholders who rely on the SysTrust-certified data center that we maintain for our EPrescribing and secure electronic messaging applications. We believe that adopting our suggested revisions will result in a final rule that fosters widespread adoption of EPrescribing and contributes to significant cost savings and reduction of medical errors, while continuing to protect the Medicare and Medicaid programs against risk of abuse in the way that Congress intended when enacting the MMA.

Electronic Prescribing Exception: § 411.357(v)

Structural Comment

Zix Corporation believes that, as presently drafted, the proposed exception places an unreasonable degree of risk on DHS entities that sponsor programs to distribute free electronic prescription technology. Specifically, the proposed exception's requirements that a device actually be used[2] and also "used solely"[3] in connection with an approved electronic prescription program place a DHS entity sponsor at significant risk of

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[2] Proposed 42 C.F.R. § 411.357(v)(2), 70 Fed. Reg. at 59197.

[3] Proposed 42 C.F.R § 411.357(v).

violation in the event a physician engages in conduct beyond the sponsor's control, such as using the device for a purpose other than electronic prescribing or failing to use the device at all. DHS entities sponsoring deployment of electronic prescribing technology have no way of monitoring or precluding use of devices and connectivity for multiple purposes because vendors that provide the hardware cannot control the use of the devices outside of the EPrescribing context. As a result, a sponsor may bill for DHS provided as a result of a referral from a physician who uses a device for clinical purposes that are complimentary to, or perhaps even unrelated to electronic prescriptions. For example, use of a device to run software made available under the proposed exceptions at 411.357(w) or 411.357(x), each of which requires that electronic medical records software include electronic prescribing functionality, is one use of the device that appears not to be subject to exception under the present proposed rules. Zix Corporation believes this is a structural flaw in the proposed rules and urges CMS to revise its approach to the "used solely" requirement, and to exercise its discretion to adopt an exception for multiple-use devices and connectivity in the manner more particularly described below.

"Used Solely"

The proposed exception reflects the requirement of the MMA that the items and services provided to the physician be "used solely" for the transmission or receipt of electronic prescribing information.

Response: As interpreted by CMS in the preamble to the proposed rule,[4] this requirement makes the exception of little practical value and is entirely at odds with the underlying purpose of the MMA in requiring the establishment of the exception, *i.e.*, the expansion of electronic prescribing. We encourage CMS to consider that electronic prescribing occurs most frequently in a clinical context where a physician must access and create information about the patient to make a diagnosis and prescription in accordance with the appropriate standard of care. It is unrealistic to think that a physician would utilize one computer or handheld to perform some aspects of patient care and an entirely separate device to generate the electronic prescription information. Zix believes that a more realistic approach would be to provide that a device or connectivity will be deemed to be "used solely" for the transmission or

[4] 70 Fed. Reg. at 59185.

receipt of electronic prescribing information if it (a) is used in connection with the receipt or transmission of electronic prescription information conforming to the then current standards under Medicare Part D; and (b) also is used for one or more of the following complimentary purposes:

1. Creating clinical documentation (*e.g.*, dictation, treatment notes)[5]
2. Accessing patient documentation or test results[6]
3. Clinical decision support (*i.e.*, reviewing online medical references, accessing clinical guidelines, reviewing the medical literature, responding to automated alerts and reminders)[7]
4. Obtaining information from payers for treatment coverage and co-payment amounts for medical services or determining whether a specific service has been pre-authorized
5. Capturing encounter data for claims purposes[8]
6. Reviewing patient schedule[9]
7. Accessing/updating on-line medication administration records[10]
8. Voice or text-based electronic communication with the patient, other clinicians, providers or payors (*i.e.*, using the handheld device to call or email someone)

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[5] A physician could use a software application to assemble a note or dictate a note to an audio file for immediate or later transmission to an electronic medical record or transcription service offered by a third party application service provider.

[6] Software provided by a third-party application service provider would enable display of medical test results on a hand-held device, either through independent connectivity or through interface with a hospital's medical record.

[7] Software on the hand-held device would enable the physician to access content supplied by a third-party provider, using connectivity that may be provided by yet another service provider.

[8] Physician enters requisite coding information to initiate billing for each patient encounter using a software application on the hand-held device. Information is transmitted directly to a local server and, from there, to a server hosted by a third-party application service provider. The application service provider then formats the information into a bill, which is then sent to the patient or payor.

[9] Using software on the hand-held device, the physician looks up a schedule for the date of the proposed appointment.

[10] Using software on the handheld device the physician documents that specific therapeutic medications have been administered to the patient. This information may then be transmitted to support claims generation or to become part of the patient's medical record.

We believe the above-described approach to the "used solely" requirement enhances the utility of the proposed exceptions by enabling physicians to use devices received under the exception to realize efficiencies in clinical practice.

Performance of some or all of the above-referenced complimentary activities would be enhanced through bundling of software functionalities in the device itself. While we understand CMS's concerns about the potential for abusive arrangements relating to bundled software, we do not believe that the value of the additional software functionality creates an incentive of sufficient magnitude to lead to abuse. We note that CMS has proposed exceptions for electronic medical records technology[11] that mandate incorporation of EPrescribing functionality to facilitate the goals of the MMA. We believe our approach to the "used solely" requirement similarly would enhance access to electronic prescribing technology by permitting incorporation of other functionality necessary to medical decision making that is of lesser value than the electronic medical records functionality excepted by the proposed exceptions in proposed 411.357(w) and (x).

At a minimum, we believe that any resolution of CMS's concerns in this regard must take into account the realities about the clinical context in which electronic prescribing occurs, and the types of information that a physician must have available to function appropriately in that context. We believe that such a solution should encompass software that provides functionality for one or more of the above-referenced complimentary purposes. CMS's proposal to provide separate treatment for devices and connectivity would not address this practical consideration in the context of clinical decision making. By way of example of the approach we suggest, CMS might elect to specify the types of functionality for software that may not be made available under the exception, rather than creating a sweeping prohibition against any bundling of software in a way that does not meet the exigencies of clinical practice.

We note that our approach also can be harmonized with CMS's approach to the prohibition in the current proposed exception that would prevent a physician from accepting duplicative technology, such as an additional handheld device limited to EPrescribing if he or she already has a handheld device that could perform such functionality if it had the

[11] Proposed 42. C.F.R. §§ 411.357(w), (x), 70 Fed. Reg. at 59197.

appropriate software drivers and applications. Specifically, in our view a device pre-loaded with bundled software that integrates electronic prescribing technology with software to support any of the above-referenced complimentary activities would be an upgrade that "significantly enhance[s] the functionality of the item or service" and therefore within the scope of permitted donations under the existing exception.[12]

Additional Exception for Multi-Functional Hardware and Connectivity Services

CMS proposed using its regulatory authority to create an additional exception for the provision by DHS entities to physicians of hardware (including necessary operating system software) and connectivity services that are used for more than one function, so long as a "substantial use" of the item or service is to receive or transmit electronic prescription information.[13]

Response: Regardless of whether CMS elects to modify its approach to the "used solely" requirement, Zix Corporation believes that it is imperative that CMS exercise its discretionary authority to create an exception for the provision of multi-functional hardware or connectivity services. If CMS maintains a restrictive interpretation of the "used solely" requirement, the additional exception for e-prescribing devices and connectivity is the only exception that will have practical value, since most physicians will choose to use hardware with multi-functional capabilities. As noted above, an exception for multiple uses also would be required in order to use the hardware or connectivity services made available under 411.357(v) to run the software made available under 411.357(w) and (x), and to provide protection for DHS entities that sponsor deployment of electronic prescribing technology against potential violations arising from use by physicians of the device or connectivity for unapproved purposes. For these reasons alone, CMS should strongly consider adopting a multi-use exception.

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[12] 70 Fed. Reg. at 59185.

[13] *Id.*

Definition of Substantial Use

The preamble to the proposed rule provides that the proposed exception for multi-functional hardware and connectivity services would be limited to situations where EPrescribing was a "substantial use" of the device or connectivity being provided.[14] CMS is soliciting public comment regarding an appropriate definition of "substantial use" in the context of electronic prescribing technology and its use.

Response: Zix Corporation proposes that, in the event CMS elects to limit a multi-function use exception to devices and connectivity for which electronic prescribing is a "substantial use", the term "substantial use" should be defined as follows:

> "For purposes of this paragraph, 'Substantial Use' means that the device is to be used to transmit or receive information in connection with electronic prescribing conforming to the then current standards under Medicare Part D; and one or more of the following activities:
> - Creating clinical documentation (*e.g.*, dictation, treatment notes);
> - Accessing patient documentation or test result;
> - Clinical decision support (*e.g.*, reviewing online medical references, accessing clinical guidelines, reviewing the medical literature, responding to automated alerts and reminders);
> - Obtaining information from payors;
> - Capturing encounter data for claims purposes;
> - Reviewing patient schedule;
> - Accessing/updating on-line medication administration records;
> - Voice or text-based electronic communication with the patient, other clinicians, providers or payors; or
> - Similar uses relating to patient treatment."

Capping the Value of Protected Technology

In the preamble to the proposed rule, CMS indicates that it is considering (a) whether to impose a cap on the value of hardware or services that could be supplied legitimately under the proposed exception for multi-

[14] *Id.*

functional devices and connectivity services;[15] and (b) whether to limit the aggregate fair market value of all items and services provided to a physician from a single donor.[16] CMS has solicited public comment with regard to (1) the nature and amount of any cap that should be imposed on the value of donated multi-functional hardware or connectivity services; (2) the amount of any aggregate cap; (3) the methodology used to determine an aggregate cap; (4) whether the same cap would be adequate if there were protection for the donation of multi-functional hardware and connectivity services; (5) whether the cap should be reduced over time; and (6) whether the cap places a disadvantage on smaller entities that do not have the financial resources of larger chains or organizations.

Response: Zix Corporation opposes the proposed caps. Zix Corporation believes that is would be premature to impose a cap at this time as the technology is highly diversified and the market not yet mature. Until there is a realistic way to assess the typical value of sponsored technology and services, we believe CMS should not impose a cap on the value of hardware or services that could be supplied under any or all of the proposed exceptions. Specifically, we believe a cap to be ill-advised for the following reasons:

(a) There is insufficient data about a typical suite of technology that would facilitate expanded use of electronic prescribing to serve as a basis for a decision about where to draw the line between an appropriate donation and a donation that risks creating undue potential for program abuse from referrals in exchange for the donation;
(b) History shows that the market will independently regulate pricing for computing technology and connectivity services to reduce the cost of technology over time in connection with the ongoing pace of technological advancement;
(c) Electronic prescribing software and services, devices and connectivity likely will be provided by independent vendors who will not necessarily be aware of the value of the items or services provided by the others;
(d) The value of the technology to be provided under the exceptions is not so substantial that it is likely to influence physician behavior;[17]

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[15] 70 Fed. Reg. at 59185.

[16] 70 Fed. Reg. at 59186.

[17] For example, the present market value of electronic prescribing services to an

(e) Requiring physicians to pay for components of service above a cap would substantially reduce the potential for diffusion of the technology;
(f) Developments in pricing, payment modality, and market delivery for electronic prescribing services and equipment (described in more detail below) are difficult to predict and a cap identified without clearer understanding of these areas could prove unduly constraining.

Zix Corporation believes that under these circumstances, imposing a cap would frustrate not further the goals of the MMA by placing artificial limits on the potential value of technology and services available to be included in programs without a clear sense of what is needed to achieve the goal of increasing use of electronic prescribing.

In the event that CMS elects to impose a cap notwithstanding the above-described objections, Zix Corporation strongly opposes adoption of a fixed dollar amount, such as the $300 limit on non-monetary compensation reflected in 42 C.F.R § 411.357(k). To be effective, a cap on the value of donated electronic prescription technology cannot approach the potential donation from the perspective of a one-time purchase. Rather, any cap would need to be flexible enough to address variations and developments in pricing, payment modality, and market delivery, and likely would need to cover a span of several years or renew on an annual basis. In our view, the most sensible way to determine any cap would be to align its structure with the realities of the costs and fee structure of hardware, software and/or services that it would cover. Of particular importance in this regard are the following:

1. License fees: Connectivity services and access to hosted[18] software applications usually are priced on a subscription basis, subject to an annual or monthly fee.

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individual physician amounts to less than one percent (1%) of the median gross income for primary care physicians in 2003. *See* Medical Group Management Association, 2004 Physician Compensation and Production Survey (describing median 2003 compensation for primary care physicians as $156,902).

[18] With respect to EPrescription software, a "hosted" application is one where the first full data record representing the electronic prescription is built off-site, using centralized equipment owned, run, and located at an entity other that the provider (*i.e.*, a clearinghouse) and the first electronic transmission of the electronic prescription is from that entity. A non-hosted application involves initial construction and electronic transmission of the data record representing the electronic prescription on equipment at

2. Training fees: Training is a normal component of a package relating to licensing of hosted software; however, it often is priced separately from the principal software license and may include per diem or reimbursement components that could change over time.
3. Support and maintenance fees: Support and maintenance often is purchased separately from the license to hosted or non-hosted software, connectivity services, or equipment. Pricing can vary dramatically, depending on the type and nature of the support and maintenance service involved
4. Initial device costs: Due to the short retail life cycle of a microcomputer, pricing for devices with comparable functionality can vary widely depending on how long the particular device has been on the market. Nonetheless, a device that has been on the market longer and has a correspondingly lower market value may require more frequent upgrades (*e.g.*, operating system, memory) to perform properly as software develops. Upgrades often are made available to existing users free or for at substantial reductions from retail costs.
5. Device (non-OS) upgrades: Upgrading an old device to a newer model to integrate better with a new version of the hosted software.
6. The rapid pace of technological change in this area, particularly if upgrades and enhancements would be considered to be "new" (*i.e.*, non-duplicative) donations.
7. Renewability: license fees often renew on a periodic basis, sometimes at lower levels than the initial license.
8. Changes in Payment Methodology. Shifts in payment methodology from a guaranteed fixed fee per physician user to a combined subscription and performance component.

CMS's preamble to the final rule establishing E-Prescribing standards[19] provides further support for range of potential value associated with sponsorship of electronic prescribing programs. For example, there appears to be broad agreement that minimum EPrescribing start up costs for each physician in terms of hardware and software is approximately $1,500.[20] Such costs do not include connectivity, license fees, or support and maintenance which are reported at $1690 per year in one case and

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the provider's site.

[19] Centers for Medicare and Medicaid Services, Medicare Program, E-Prescribing and Prescription Drug Program (Final Rule), 70 Fed. Reg. 67568 (Nov. 7, 2005).

[20] 70 Fed. Reg. at 67587-88.

between $80 and $400 per month in other cases.[21] Where implementation costs can reach and exceed $4,300 per physician for EPrescribing systems alone,[22] when such systems are bundled with other functionality, it is no surprise that costs for an electronic health record with integrated EPrescribing functionality could exceed $9,000 per physician.[23] Zix Corporation believes that the substantial range of value of an EPrescribing program depending upon how many of the technology components and services it includes precludes imposition of a meaningful fixed dollar amount cap. In our view, a scalable cap that can accommodate the potential for variation among components of EPrescribing programs is the only effective way to implement a cap consistent with the MMA's goal of promoting adoption and deployment of EPrescribing technology.

In light of the foregoing considerations, Zix Corporation urges CMS to approach its decision regarding restrictions on the value of donated technology with the same degree of flexibility and pragmatism it employed in providing for profit-sharing and productivity bonuses under the group practice exception set forth at 42 C.F.R. § 411.352(i)(2). Specifically, CMS provided physician practice groups with multiple options for structuring physician compensation that balanced productivity incentives with concerns about potential program abuse. CMS could achieve the same balance between productive innovation and program protection by taking multiple approaches to donations. Such approaches might include limitations on donations covering a multi-year period that takes into account the value of both the hardware product, as well as the service subscription and software support and maintenance fees that likely will recur on an annual basis. Other options include looking for ways to value the service other than the fees paid by the donor, in order to take into account the potential for risk-sharing mechanisms to develop within the industry that enable third-party service providers to reap additional economic benefits from effective services in ways that may not change the

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[21] *Id.* at 67589.

[22] *Id.* at 67588.

[23] Highmark, Inc. a Pennsylvania licensee of the Blue Cross Blue Shield Association, has contributed $26.5 Million to fund a program administered by the Pittsburgh Foundation that will pay up to 75% of the cost for a physician's office to acquire, install and implement an electronic technology system up to a maximum of $7,000 per physician. *See Highmark, Inc. Contributes $26.5 Million to Fund Organization that Encourages Adoption of Health Information Technology*, (Nov. 15, 2005), available at https://www.highmarkehealth.org/images/E-Prescribing_110905.pdf (visited Dec. 9, 2005).

value of the core service to the physician. For example, a service provided might charge a sponsor a lower basic service subscription in exchange for the opportunity to share in savings that accrue from increased formulary compliance or prescription of generics. In this type of situation, focusing simply on either the subscription fee or the aggregate payment from the donor would misstate the value of the service.

Although Zix Corporation believes the best course of action would be to avoid a cap entirely, a suite of restrictions that provide the above-described kind of flexibility could provide an effective balance of encouraging increased adoption of electronic prescribing and protecting federal health program integrity.

42 C.F.R. § 411.357(v)(2)

Subsection 2 of the proposed exception requires that the items and services provided to the physician be part of, or used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the same are furnished.

Response: As noted at the outset of this comment, Zix Corporation is concerned that, as presently drafted, this requirement creates the potential for a Stark violation by an entity that bills for DHS provided as a result of a referral by a physician who obtains electronic prescribing technology donated by the DHS entity, but who fails to utilize it. While Zix Corporation appreciates the need to ensure that the benefits and efficiencies of electronic prescribing technology redound to the Medicare program, we believe it is inappropriate to penalize donors for recipients' failure to use a device or other technology. We are particularly concerned that maintaining the existing language will cause donors to require vendors such as Zix Corporation to engage in onerous monitoring and reporting obligations relating to individual physician use of donated technology. Such obligations could divert resources and significantly increase the costs and reduce the efficiency of electronic prescription services without materially enhancing the benefits to be realized from the service provided. We believe that a rephrasing of 411.357(v)(2) in the manner set forth below would address CMS's legitimate concerns in the area without the above-described undesirable consequences:

"(2) The items and services are donated as part of, or for use in connection with an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are furnished, and the contract with the physician provides that the donor may redeploy the device or service to another physician if the receiving physician fails to write a specific number of prescriptions using the service within a certain period of time."

Other DHS Entities.

CMS has solicited comment on whether it should use its discretionary authority to establish protections for electronic prescription technology and services provided to physicians by DHS entities other than those described specifically in the MMA.[24]

Response: Zix Corporation encourages CMS to use its discretionary authority to protect donations of electronic prescription technology and services to physicians by the following types of entities: Health care delivery systems, pharmacy distribution channels, including retail and mail order pharmacies, pharmacy benefit managers and insurance companies, and suppliers of prescribable non-drug items and services. We believe that, to the extent these entities do not directly provide DHS, they may, by virtue of their relationship to PDP sponsors, create the potential for indirect compensation arrangements between DHS providers and physicians unless an exception applies. We believe that these entities are equally or more likely to be interested in fostering the diffusion of electronic prescribing technology than those entities specifically listed in the statute. Our support for expanding the scope of the exception to include prescriptions for non-drug items and services (discussed at p. 12 below) also motivates us to advocate inclusion of suppliers of such services among those entities able to benefit from the protection of the exception.

[24] 70 Fed. Reg. at 59186.

"Interoperability"

CMS has indicated that is considering imposing an "interoperability" requirement, such that the DHS entity (and agents thereof) offering the technology to the physician would be prohibited from taking any actions to disable or limit the compatibility interoperability of the technology with other information products.[25] CMS is considering defining 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." CMS is soliciting public comment regarding this requirement, its definition of "interoperable," alternative means of ensuring the maximum level of interoperability, and the types of software currently available for electronic prescribing.

Response: Zix Corporation supports the concept of interoperability to the extent that it means establishment of standards that foster communication among and between separate proprietary platforms. We would oppose a definition of "interoperability" that required Zix Corporation to accept and support transmissions from devices supplied by other vendors, or to require us to make our hosted applications accessible by software in other vendor's devices.

In connection with to the actual development of standards for interoperability, Zix Corporation also strongly supports implementation of a mandatory compliance regime that would include (a) a compliance deadline; (b) transition rules; and (c) enforcement authority and penalties for noncompliance. Providers of EPrescribing services must interface with a variety of entities, including switching companies, prescription benefits managers and health care clearinghouses, each of which addresses different aspects of the transmission and processing of electronic prescriptions and claims. Accommodating different platforms and standards maintained by each such entity is costly. An interoperability requirement that clearly establishing a compliance date, transition rules and penalties for noncompliance offers the best possibility for effectively managing costs associated with transition to the new standards and minimizes the potential for unpredictable cost increases were business partners of EPrescribing companies to transition their systems on different timetables.

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[25] *Id.*

Use of Electronic Prescribing Technology for Non-Drug Items and Services

CMS requested comment on whether the exception should permit qualifying electronic prescribing technology to be used for the transmission of prescription information regarding items and services that are not drugs, *e.g.* supplies or laboratory tests.[26]

Response: Zix Corporation urges CMS to expand the exception to cover physician orders for the widest possible range of items and services. Many items and services that are not drugs currently are "prescribed" using a prescription pad. The same advantages to be gained through electronic prescribing of drugs can be gained through electronic orders for other items and services. In addition, if CMS fails to include non-drug items and services within the scope of the exception, EPrescribing companies will be required to establish separate workflows for drug prescriptions and non-drug prescriptions. Zix Corporation believes that requiring separate workflows would be impractical and would have a chilling effect on the adoption of EPrescribing technology.

42 C.F.R. § 411.357(v)(6)

Subsection (6) of the proposed exception requires that neither the eligibility of a physician for the items or services, nor the amount or nature of items and services, be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

Response: As presently drafted, this requirement appears inconsistent with the purpose of encouraging broader use and adoption of EPrescribing technology, as well as some of the practical realities of the marketplace. A health plan sponsor of an electronic prescription program has a legitimate need to take into account the anticipated amount of use a particular physician will make of an electronic prescription service in deciding whether (a) it makes sense to facilitate the physician's access to the technology in the first place; and (b) to continue to make the electronic

[26] 70 Fed. Reg. at 59186.

prescription service available in situations where the service is provided on a subscription basis. While we appreciate CMS's desire to reduce the potential that an entity will provide access to EPrescribing technology and services on a quid pro quo basis rather than for sound business reasons, we believe that appropriate exceptions must be made to accommodate those aspects of program sponsorship that have a legitimate business purposes and that likely will not lead to abuse. The following example illustrates what we believe to be legitimate, nonabusive use of prescription volume information by a health plan sponsor in assessing eligibility for physician participation in an electronic prescription program:

> A health plan sponsor of an EPrescribing promotion seeks to realize cost savings from the deployment of the e-prescribing item or service by enhancing formulary compliance, reducing claims processing costs, and reducing costs by encouraging prescription of generic or multi-brand drugs. Under these circumstances, the sponsor obtains the greatest value from its investment in the EPrescribing technology if that technology is deployed to physicians who write large numbers of (paper) prescriptions. The only source of data regarding prescriptions that will be available to the health plan sponsor to assess potential recipients of EPrescribing technology will be the prescriptions written for individuals covered by that health plan. In the most likely scenario, the health plan would use its data to identify potential candidates for an EPrescribing promotion and provide contact information for those physicians to a third party vendor of electronic prescription technology or services, who would then contract with the physicians to provide the items or services that will be paid for by the program sponsor. Electronic prescription services often are charged on a subscription basis involving a flat fee for a period of service, regardless of the number of transactions. Such fees will enable health plans to effectively manage their investment in the EPrescribing program but, because the costs are fixed, a sponsor of an arrangement structured in this way will want to ensure that the physicians actually use the technology. Accordingly, volume of prescriptions processed electronically is the most effective measure for use of the service, but once again, the sponsoring plan will only have access to data relating to its covered individuals.

In light of the above example, we recommend that CMS revise proposed 42 C.F.R. § 411.357(v)(6) to provide that a determination will be deemed not to relate to the volume or value of referrals or other business generated between the physician and the DHS entity if it meets one of the following criteria:

> "(i) The determination is based on whether the recipient's total number of prescriptions (or electronic prescriptions) written for individuals covered by a health plan sponsor of an electronic prescription program exceeds a specific threshold that is set in advance;
>
> (ii) The determination is based on the total number of prescriptions (or electronic prescriptions) written by the recipient;
>
> (iii) The determination is based on the total number of the recipient's patients who are covered by the health plan sponsor of an electronic prescription program
>
> (iv) The determination is based on the recipient's overall use of computer technology in his or her medical practice;
>
> (v) The determination is based on whether the recipient is a member of the medical staff of a hospital, if the hospital is the donor; or
>
> (vi) The determination is based on whether the recipient is a member of the medical staff of a hospital that serves a significant number of patients who are covered by the donor, if the donor is a health plan."

Zix Corporation believes that our position on this issue is consistent with CMS's approach to encouraging broad dissemination and adoption of approved electronic medical records software. CMS's proposed approach to such software appears to reflect some understanding of the legitimate uses of information about prescription volumes. For example, proposed 42 C.F.R. § 411.357(x)(4) provides that a determination will be deemed not to relate to the volume or value of referrals or other business generated between the physician and the DHS entity if the determination is based on (a) the total number of prescriptions written by the physician; (b) size of medical practice or (c) overall use of automated technology within the medical practice.[27] We believe that CMS may have overlooked the fact that such information likely will only be available through self-reporting by the recipient and will not be independently verifiable.

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[27] 70 Fed. Reg. at 59198.

Obtaining the information required by CMS under section (x)(4) could add significant administrative costs and burdens that may discourage potential sponsors from donating technology. By contrast, the information described in the additional criteria proposed by Zix Corporation in the language above (items (i), (iii), and (vi)) is readily available to and independently verifiable by a potential health plan sponsor. Zix Corporation urges CMS to adopt this concept in the final electronic prescribing exception, and that it broaden the scope of the exception to better suit the electronic prescription context by including information available to a health plan sponsor by adopting the language suggested above.

42 C.F.R. § 411.357(v)(7) ("Written Agreement")

Subsection (7) of the proposed exception provides for a written agreement between the DHS entity and the physician.

Response: As presently drafted, this requirement is not consistent with existing reality in the implementation of device and connectivity programs. Agreements for hardware, training support, and, in some cases, wireless connectivity services are made between the physician and the electronic services provider, such as Zix Corporation's subsidiary, PocketScript. The donor DHS entity and the electronic services provider (*e.g.*, PocketScript) will have a separate agreement, under which the donor pays PocketScript to deploy the electronic prescription technology and services to an identifed group of physicians. Requiring an agreement between the DHS entity and the physician would insert the donor into the transaction between the physician and services provider. Requiring the health plan or other sponsor to be part of this contracting relationship would cause significant inefficiency, delay, and increased paperwork relating to the transaction.

Zix Corporation is concerned that, if implemented, this requirement will reduce the ability of potential sponsors who are not able to support the additional contracting volume to make available EPrescribing technology and services. At a minimum the requirement will significantly increase the time and process necessary to implement a program. These requirements could impose significant burdens that ultimately could cause breakdowns in the implementation of the program or substantially increase the time and cost associated with deployment. We believe such a result

would be contrary to the purposes for which the exception was required to be promulgated under the MMA. Zix Corporation urges CMS to revise the written agreement requirement to permit the required "agreement" between physician and donor to be accomplished indirectly, through a combination of agreements among the physician, third-party technology or service provider, and donor.

42 C.F.R. §411.357(v)(7)(iv) ("Technical and Functional Equivalence")

Paragraph (iv) of subsection (7) of the proposed exception requires that the written agreement contain a certification by the physician that the items and services are not technically or functionally equivalent to items and services he or she already possesses or has obtained. In the preamble to the Proposed Rule, CMS states that "the provision of a second hand-held device would not qualify for the exception if the physician already possesses a hand-held device that could run the [electronic prescription] software."[28]

Response: Zix Corporation believes that with respect to hand-held devices, a device should not be viewed as technically or functionally equivalent to one that a physician already possesses if the existing technology did not have electronic prescribing capability. We appreciate CMS's clarification in the preamble that handheld and desktop computers are not technically or functionally equivalent; however, we are concerned that preventing physicians who have an existing handheld device from obtaining a donated device with EPrescribing functionality will place substantial limits on the diffusion of electronic prescription technology. Zix Corporation believes that a new hand-held device that includes electronic prescription software is an upgrade of equipment that "significantly enhance[s] the functionality of the item" and should not be considered technically or functionally equivalent.

Our view is based on the dynamics of fulfilling orders in the mobile technology industry. Specifically, like most similar operations, PocketScript is organized to provide new subscribers with new handheld devices to write electronic prescriptions that have our proprietary EPrescribing application pre-installed. The installation is performed in a mechanized fashion as part of the technology deployment process in our

[28] 70 Fed. Reg. at 59184–85.

offices or a contracted fulfillment center. We do not have the service and support force to install the software on existing devices and, even if we were to establish such a force, it would substantially increase the cost of service without adding additional value to either the sponsor or physician. Most importantly, due to the difficulty of scheduling physicians' time, the distribution of new, pre-installed devices would remain the most effective means of obtaining the technology. CMS's current interpretation of technical and functional equivalence also would preclude a vendor from deploying a device to a physician who had EPrescribing service from a competitor. We believe that approach presents a significant barrier to competition and will stifle innovation in the electronic prescribing field by tying physicians to their existing service providers.

For the foregoing reasons, Zix Corporation believes that the certification requirement is inappropriate in the context of the mobile technology fulfillment industry and should be eliminated from the exception. In the event that CMS decides to retain the certification requirement, Zix Corporation believes that, at a minimum, the requirement should be revised to focus on devices or connectivity that are used for electronic prescribing. We believe that if CMS revises its approach to the definition of "used solely" to incorporate the activities described beginning on page 3 of this comment letter, it would be appropriate to preclude replacement of devices that can be used for that suite of activity. As noted above with respect to the written agreement requirement, Zix Corporation also believes CMS should revise the certification requirement to permit the certification to be included in the agreement between the physician and the technology or service provider, and to mandate that the DHS entity require the technology or service provider to obtain the certification in the overarching contract governing the program as a whole.

Costs of obtaining EPrescribing technology

CMS also sought comment on the retail and non-retail costs of obtaining electronic prescribing technology and the degree to which physicians may already possess items or services that could be used for electronic prescribing so as to be fully informed on this matter.[29]

[29] 70 Fed. Reg. at 59186.

Response: Zix Corporation is able to provide the following data and information to assist CMS with respect to understanding the current financial realities in the electronic prescription arena. The costs of providing electronic prescription services can be divided into the following several categories:

1. Cost of the hardware device
2. Cost of recruiting the physician
3. Installation of software on the hardware
4. Deployment/fulfillment process, including
    a. site survey to confirm IT infrastructure, and nature and extent of wireless and Internet access
    b. installation
5. User training (*i.e.*, physician and staff)
6. On-going technical support and system monitoring
7. Software licensing
8. Corporate overhead
9. Software development man-hours required to implement feature and functionality upgrades, requirements, and enhancements mandated by changes in regulations, business partners, or program sponsors.

Of these categories, only the cost of the hardware device currently has an established market price. Further, increased penetration of the technology will result in decreases in the cost over time. Unfortunately, due in part to the regulatory restrictions on various types of arrangements, it is not possible currently to predict the rate of adoption of electronic prescription programs in any meaningful way.

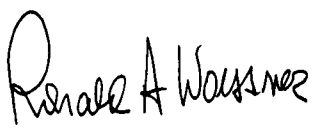
Electronic prescription services is a developing market and the data presently available is of scant predictive value because expectations regarding pricing and payment practices likely will evolve significantly over a short period. For example, we anticipate that there will be shifts in payment methodology from a guaranteed fixed fee per physician user to a "pay for performance" component that seeks to share savings accrued from increased formulary compliance or prescription of generics in exchange for a lower basic service subscription. We also anticipate that there will be shifts in method of delivering the sponsored technology or services to the market, including bundling of services with electronic medical records in the manner encouraged by proposed Section 411.357(w) and (x). These types of changes in payment modalities market

delivery method are characteristic of the development of other disruptive interventions in the prescription benefits industry, most notably with respect to prescription benefits managers and mail order pharmacies, and we expect them to apply in the electronic prescription context as well.

We hope CMS finds this information useful. For further information or if we may offer additional assistance, please contact the undersigned at 214.370.2219.

Respectfully submitted,

ZIX CORPORATION



Ronald A. Woessner
Senior Vice President and General Counsel

Submitter : **Mr. Pete Stark** **Date: 12/12/2005**

Organization : **Office of Representative Pete Stark**

Category : **Congressional**

Issue Areas/Comments

Issue

Background

See Attachment

Provisions of the Proposed Rule

See Attachment

CMS-1303-P-35-Attach-1.DOC

December 12, 2005

The Honorable Mark McClellan, MD
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: File Code CMS-1303-P

Dear Dr. McClellan:

As the Ranking Member on the Committee on Ways and Means Subcommittee on Health, I respectfully submit the following comments on the proposed rules (CMS-1303-P) entitled "Physicians' Referrals to Health Care Entities With Which They have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements," issued October 11, 2005.

Expanding the use of e-prescribing and electronic health record (EHR) technology is an important goal. Provided it's a seamless, interoperable system, this technology will eventually lead to fewer medical errors, less duplicative services and possibly even cost savings for the entire health care system. However, in reaching that goal we should not destroy the important patient and anti-fraud protections provided by the physician self-referral prohibition (often called the "Stark laws").

I wrote these laws to help eliminate duplicative and unnecessary services done only for the financial benefit of providers. By allowing exceptions for technology that is not yet interoperable, the proposed rules may create new incentives for physicians to refer directly to other providers that have helped them obtain new technology. By definition, that thwarts the intent of the Stark laws. Arrangements that create those incentives should never receive an exception.

I have no doubt that CMS fully intends to adopt these rules regardless of my comments. However, the public has a right to know that we are headed down a dangerous path. These proposed rules focus more on the financial enrichment of physicians and

hospitals than on patient safety and reducing fraud in federal health care programs, or even on facilitating a thoughtful expansion of the use of information technology in the health community. We have a long way to go before this technology is widely adopted, and these proposed rules must be strengthened substantially before any new exceptions are created to the Stark laws.
Furthermore, it's not clear to me that new exceptions are needed, even after uniform standards for interoperability are in place. If hospitals and other providers want to provide technology to physicians, they could do so by giving donations to unaffiliated non-profit community foundations that help physicians obtain medical technology. This type of donation would ensure that there are no unnecessary incentives for physicians to refer to providers who have directly donated e-prescribing or EHR technology.

Electronic Prescribing Exceptions: § 411.357(v)

The final rule should not go into effect until there are federal interoperability standards for e-prescribing. Unless technology is interoperable, a physician with privileges at multiple hospitals will probably refer to the facility with the same e-prescribing system -likely the hospital that gifted the technology. This arrangement clearly violates the intent of the Stark laws and should not receive an exception.

Once interoperability standards are in place, CMS must tighten the final rule to further ensure physician referral occurs for the right reasons. The proposed rule creates an exception for certain providers to give e-prescribing technology to physicians, as long as that technology is "necessary and used solely to receive and transmit electronic prescribing information." The final rule must clarify what e-prescribing software and hardware will be allowed under the "necessary and used solely" requirement. The regulations must further state that providing additional financial, accounting, or practice management software to a physician is not allowed under the exception (though the vendors could sell such add-ons directly to the physicians).

Finally, if all e-prescribing technology is interoperable, there is no reason a party providing this technology to a physician should not provide the same offer to all affiliated physicians. A group practice cannot be allowed to offer technology only to the top performing doctors in the group. Doing so has the potential to reward or penalize providers based on their referral or utilization patterns. A hospital must offer the same technology to every physician on staff. This is the only way to ensure physicians are not given technology as an incentive to generate referrals.

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

This proposed rule should be eliminated entirely. Allowing myriad non-interoperable proprietary systems to proliferate will entrench those who buy or use these systems and move the community away from an interoperable structure just as it might be possible. In addition, it would likely lead to physicians referring patients to providers with similar technology. Electronic health records (EHR) that are not interoperable will likely lock physicians into relationships with the providers giving away this technology, and those providers will be locked into relationships with the vendors from whom they've purchased the equipment. Once again, this induces referrals and clearly violates the intent of the Stark laws. Providing EHR technology before these systems are interoperable should not receive an exception from the Stark laws under any circumstance.

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

Consistent with previous statements, I believe a very limited Stark law exception is appropriate after a real federal standard for interoperable electronic health records (EHR) is adopted. These standards must not be glossy ideas of how interoperable systems will work. The standards must specifically state what must be included in an EHR and how that information can be exchanged between responsible parties. Interoperability standards must also contain strong privacy protections so that patients maintain sufficient control over how and why an EHR is being accessed.

Assuming CMS or HHS can create sufficient federal interoperability standards, the final rules must contain additional protections so as to avoid improper referrals. The definition of what qualifies as an EHR must be narrow, avoiding the provision of other extraneous software and hardware to physicians. Additional financial, accounting, or practice management software must be specifically disallowed. The definition must also require the systems in question to interact with public health information networks.

Prescription Drug Plans should be specifically excluded from the list of protected donors allowed to provide EHR technology. The only incentive these plans would have to offer EHR technology to physicians is in return for steering patients toward their particular drug plans and formularies.

If systems are fully interoperable, there should be no incentive for physicians to refer patients based on who provides the EHR technology. All physicians affiliated with a protected donor must receive the same EHR donation offer. This ensures that donors do not favor high-revenue or high-volume physicians merely because they are likely to generate more business through an increased volume of referrals.

Sincerely,

Pete Stark
Member of Congress

Submitter : Mrs. Melissa Speck

Date: 12/12/2005

Organization : The Hospital & Healthsystem Association of PA

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1303-P-36-Attach-1.DOC

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

December 12, 2005

Mark B. McClellan, M.D., 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

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

Dear Dr. McClellan:

On behalf of the Hospital & Healthsystem Association of Pennsylvania, we endorse the comments to the proposed regulation as submitted by The National Alliance for Health Information Technology, as well as the American Hospital Association. The recommendations made in both The National Alliance for Health Information Technology's comment letter submitted to the Centers for Medicare & Medicaid Services (CMS) dated December 8, 2005, as well as the comment letter submitted to CMS dated December 5, 2005, by the American Hospital Association, reflect a consensus view in the health care field that the regulation as proposed will not achieve the goal of promoting the widespread adoption of health information technology and its productive use by hospitals and physicians.

The American Hospital Association and The National Alliance for Health Information Technology's comments detail the potential impact and concerns regarding the proposed regulation by the hospital and physician community. Remedies to the unintended inhibiting effects of the proposed regulation are necessary if we are to reach the goal of increasing physician usage of information technology and expanding information exchange.

We appreciate the opportunity to comment on the proposed rule. We urge CMS to reconsider its proposed regulation to ensure that hospitals have the flexibility needed to move forward with physicians, to integrate and increase usage of information technology as a means of improving quality care across all provider types.

Sincerely,

Carolyn F. Scanlan

CAROLYN F. SCANLAN
President & Chief Executive Officer

CFS/dd

Submitter : Mr. David McCune

Date: 12/12/2005

Organization : BJC HealthCare

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1303-P-37-Attach-1.DOC

December 12, 2005

SUBMITTED ELECTRONICALLY

TO: Centers for Medicare & Medicaid Services (CMS)
U.S. Department of Health & Human Services (DHHS)
ATTN: CMS-1303-P
P.O. Box 8010
Baltimore, MD 21244-8010

and

Office of Inspector General (OIG)
U.S. Department of Health and Human Services (DHHS)
ATTN: OIG-405-P
Room 5246
Cohen Building
330 Independence Avenue, SW
Washington, D.C. 20201

FROM: David McCune
Director, Legal Services
BJC HealthCare
600 S. Taylor Ave., Suite 154
St. Louis, MO 63110-1035

RE: Proposed Rule regarding Exceptions for Certain Electronic Prescribing and Health Records Arrangements , file code CMS-1303-P ("Proposed Stark Rule"); and Proposed Rule regarding Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute, file code OIG-405-P ("Proposed Safe Harbor Rule").

On behalf of BJC HealthCare (St. Louis, Missouri), I would like to submit the following comments in response to the Proposed Rules identified above.

GENERAL

BJC HealthCare (BJC) is one of the largest non-profit health-care organizations in the United States, with 26,000 employees and 2004 net revenues of $2.6 billion. BJC HealthCare's 13 hospitals and multiple health-care facilities deliver a comprehensive array of medical services in the greater St. Louis, southern Illinois and mid-Missouri regions. Services include inpatient and outpatient care, primary care, community health and wellness, workplace health, community mental health, rehabilitation, home health, long-term care and hospice.

BJC HealthCare strongly agrees there is a need for rapid, widespread adoption and implementation of interoperable, interconnected electronic prescription and electronic health record technology as a means of both reducing medical errors and improving efficiencies within the industry. For this reason, BJC already has invested significant resources toward the improvement of its own technical capabilities and desires to assist in the dissemination of e-prescription and electronic health record capabilities to health care providers practicing incommunities served by BJC.

BJC appreciates and supports the efforts of both CMS and the OIG in promulgating these proposed rules. However, we also feel that the scope of each of the proposed rules has been too narrowly defined to achieve the stated objective of promoting the rapid adoption of this technology. We recognize the limitations of CMS' statutory authority in this regard. Thus, BJC

urges adoption of broader rules than present statutory authority would permit and adds its voice to those urging Congress to enact broader flexibility for CMS and the OIG in this area. Our specific comments to each of the proposed rules is set forth in further detail below.

PROPOSED STARK RULE

A. Electronic Prescribing Exception: § 411.357(v)

1. **The limitation to hospital medical staff is too restrictive.** While again recognizing the limitations in CMS' statutory authority on this issue, we believe that it is a mistake to limit a hospital's ability to donate e-prescribing technology only to those physicians on its medical staff. In our view, this condition seems contrary to CMS' desire to protect against hospitals using donations as a means of inducing physicians to join the medical staff of a different hospital. By expressly conditioning a donation on medical staff membership, the exception seems to be encouraging competitive behavior among hospitals, rather than minimizing it. So long as the other safeguards set forth in the exception are met, it would seem to matter less whether the donee is a medical staff member or not.

2. **The "used solely" standard is too restrictive.** We agree with CMS' view, expressed in the commentary, that multi-functional hardware needs to be addressed within an exception. We support CMS' proposal to establish an additional exception addressing multi-functional hardware (including operating software) and connectivity services where the "substantial use" is for e-prescribing. Therefore, we would urge the definition of "substantial use," as well as any cap on the dollar value of the donation, be set with reference to the actual types of hardware (and value thereof) predominantly employed (or anticipated to be employed) by the industry to encourage the use of e-prescribing technology.

3. **Whether a physician already possesses functionally equivalent items or services is irrelevant, given other protections.** Given the other protections against abuse of this exception, the requirement that the physician does not already possess the equivalent item or service seems unnecessary. Given that the hospital cannot: (1) limit the use or compatibility of the donated item; (2) condition the donation on the physician's doing business with the hospital; or (3) condition eligiblity for the donation on the value or volume of business generated between the parties, and given that the donation must be "used solely" for the receipt and transmission of electronic prescription information, it is unclear how the fact that the technology may be duplicative of other technology already in the physician's possession increases the risk of program abuse. On the other hand, the added requirement will likely have a chilling effect on hospitals' willingness to donate technology or services without first conducting a full inventory of the practice's current technological capabilities.

4. **The exception should apply to donations from other, non-hospital entities.** As written, the exception only permits donations from hospitals. However, we believe the exception should also apply to donations from a non-hospital organization with whom the hospital may have an affiliation or otherwise be involved with for purposes of implementing the described technologies. For instance, if a hospital participates with other healthcare organizations in a regional healthcare information organization (RHIO) that desires to make donations of e-prescription technology to physicians in the community, the exception should be crafted broadly enough to permit this. Likewise, donations from affiliated hospital foundations should be permitted. We would suggest these concerns be addressed by permitting donations by hospitals "whether made directly or indirectly."

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

1. **The comments set forth in I.A. should apply to this exception as well, with references to "e-prescription" deemed to reference "electronic health records."**

2. **BJC believes the exception should include the electronic prescribing component of EHR software used for items and services beyond pharmaceuticals (i.e. medical supplies, lab tests, etc.).**

3. **The definition of "Electronic Health Record" should be based upon the actual electronic health record technology predominantly in use (or anticipated to be predominantly used) by the medical industry to create, transmit, use and store electronic health information.**

4. **The exception may have unintended, adverse consequences.** We are concerned that the proposed exception, by at least implicitly supposing necessary restrictions on compatibility, may actually be misinterpreted as approving a window of opportunity for hospitals to spread their own, non-interoperable systems in an effort to "hook" physicians into exclusive reliance on its system. To avoid this unintended consequence, we believe that instead of creating a separate pre-interoperability exception, it would be more congruent and less susceptible to abuse to simply make the post-interoperability exception immediately available – subject to the caveat that any technology donated prior to CMS's adoption of criteria must be made to meet those criteria within some reasonable timeframe following adoption.

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

1. **Comments set forth in I.A. and I.B.1, I.B.2 and I.B.3 above apply to this exception as well.**

2. **The exception should be broadened following adoption of interoperability standards**. We agree with CMS' view that interoperability will mitigate many of the potential anti-competitive effects of a hospital's implementation of EHR technology. We believe that once CMS has adopted product certification criteria for interoperable electronic health record technology, several of the exception's requirements should be removed in the interest of encouraging broad and rapid dissemination of certified technology. In particular, we would urge the following requirements be removed from the exception upon adoption of the criteria: (1) that the donation be made available only to medical staff members; (2) that the physician certify and hospital be unaware of any equivalent items/services in the physician's possession; and (3) that the donation not violate the Anti-Kickback Statute (AKS). The fact of interoperabilty itself, taken together with the other substantial remaining safeguards, would seem to provide substantial protection against anti-competitive or abusive behavior. At the same time, removing these requirements would serve to promote more rapid dissemination of the technology by: (1) broadening the potential field of recipients beyond just medical staff members; and (2) removing the more subjective requirements, such as deciphering the parties' intent, which would be brought into play by requiring AKS compliance. In our opinion, the inclusion of these subjective requirements within this exception would only serve to cast a chilling effect on hospitals' willingness to make donations in reliance on the exception, yet would not add meaningful protection against abuse.

3. **Consistent with our comments above, we believe the definition of "core function," the scope of what is "necessary"to transmit, receive and maintain EHR's, as well as any cap on the dollar value of the donation, should be set with reference to the actual software predominantly in use (or anticipated to be in use) by the industry with regard to electronic health record technology.**

4. **The prohibition on providing staffing should be clarified to permit the provision of software support related to the donated EHR system.** Given that the hospitals will most likely purchase the relevant systems on a hospital-wide basis, it would be impractical to require each individual participating practice to separately contract for support services. To the extent the services are directly related (and limited to) the donated software, this would not appear to create meaningful opportunity for abuse.

PROPOSED SAFE HARBOR RULE

As the requirements set forth under the proposed safe harbor rule and the commentary suggesting further rulemaking to promulgate further safe harbors related to electronic health record technology appear to substantially mirror those proposed by CMS under the proposed rules discussed above, our comments to the OIG's proposals are substantially the same as set forth above.

Submitter : Carol Keehan **Date:** 12/12/2005

Organization : Catholic Health Association of the United States

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1303-P-38-Attach-1.DOC

CMS-1303-P-38-Attach-2.DOC

THE
CATHOLIC HEALTH
ASSOCIATION
OF THE UNITED STATES

December 12, 2005

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1303-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1303-P; 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.

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In short, the proposed regulations so narrowly define and restrict the terms and conditions under which hospitals may provide e-prescribing and EHR technology to physicians, that hospitals will be discouraged from doing so. In developing its final regulations, **CHA urges CMS to place first and foremost its primary goal of rapid HIT dissemination, by dramatically simplifying its requirements for hospital donation of this technology to physicians, so that the fear of reprisal under Stark (except in truly abusive situations) is all but eliminated.**

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To attain its stated goal of rapid dissemination of e-prescribing and EHR technology to physicians, **CHA recommends that CMS simplify its final rule to provide for a single, unified Stark exception which would allow hospitals to give physicians integrated e-prescribing and EHR hardware, software, and related training. Further, there should only be one certification required once final interoperability standards for all HIT components are finalized. Also, CMS should not exclude from "covered technology" the ability of a donated system to perform critical administrative functions, such as patient scheduling, billing, and referrals for necessary health care services.**

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The lack of certainty surrounding the above terms, and the burden on physicians of having to certify that all HIT gifts from a hospital do not in any way violate the proposed Stark exceptions, is extremely daunting for hospitals and physicians alike. As such, **CHA strongly urges CMS in its final rule to**

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Submitter : **Mr. Richard Latuchie** **Date: 12/12/2005**

Organization : **Regional Health, Inc.**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Submitter : Mr. Carl Faulstick **Date:** 12/12/2005

Organization : Affiliated Healthcare Systems

Category : Laboratory Industry

Issue Areas/Comments

GENERAL

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See attachment

CMS-1303-P-40-Attach-1.DOC

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CATHOLIC HEALTH
ASSOCIATION
OF THE UNITED STATES

December 12, 2005

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1303-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Dr. McClellan:

The Catholic Health Association of the United States (CHA) is pleased to submit the following comments on the above proposed rule which seeks to establish exceptions to the Stark Physician Self-Referral regulations, which would permit hospitals to: (1) provide hardware, software, and related training to physicians for electronic prescribing ("e-prescribing") and; (2) provide physicians with electronic health records (EHRs) software and related training. The stated goal of these proposed regulations is to speed the process of meeting the "President's goal of achieving widespread adoption of interoperable EHRs for the purpose of improving the quality and efficiency of health care, while maintaining the levels of security and privacy that consumers expect."

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CHA heartily endorses the underlying goal of these proposed regulations and believes health care quality, efficiency, and safety can be improved through the use of interoperable health information technology (HIT). However, in their current form, CMS's proposed regulations are more likely to have an undesired chilling effect on spreading the adoption HIT, for a number of reasons, as detailed below.

- <u>The Proposed Regulations Do Not Support and Further the Administration's Policy of Speeding Widespread EHR Adoption.</u>

From a policy perspective, the potential gains widespread HIT adoption would hold for patients and the federal government—in terms of increased quality, patient safety, productivity, care efficiency, and reduced morbidity and

mortality—would seem to far outweigh any small risk donating this technology to physicians might pose. In fact, while the e-prescribing exception was mandated under the Medicare Modernization Act (MMA), the exceptions proposed for EHRs are entirely discretionary on the Secretary's part, under Section 1877(b) (4) of the Social Security Act. This part of the law authorizes the Secretary to "create regulatory exceptions for financial relationships that he determines do not pose a risk of program or patient abuse." In essence, by proposing the EHR exceptions, the Secretary is already acknowledging that such technology donations by hospitals do *not* constitute a risk of program or patient abuse.

The very positive public health goals of these proposed regulations are further underscored by you in an October 5, 2005 press release, when you stated:

> Restrictions on relationships between physicians and other health care entities are very important for assuring Medicare dollars are spent appropriately, but they were never intended to stand in the way of bringing effective electronic health care to patients. We are bringing our rules in line with what we are working together to achieve: an interoperable electronic health care system that benefits patients by improving care, reducing complications, and unnecessary tests and procedures.

In short, the proposed regulations so narrowly define and restrict the terms and conditions under which hospitals may provide e-prescribing and EHR technology to physicians, that hospitals will be discouraged from doing so. In developing its final regulations, **CHA urges CMS to place first and foremost its primary goal of rapid HIT dissemination, by dramatically simplifying its requirements for hospital donation of this technology to physicians, so that the fear of reprisal under Stark (except in truly abusive situations) is all but eliminated.**

- <u>The e-Prescribing Exception is Too Narrow and Should be Merged into a Single, Expanded EHR Exception.</u>

CHA acknowledges that the MMA mandated that CMS promulgate a regulatory exception for e-prescribing hardware, software, and related training. However, having hospitals donate such technology to physicians as a stand-alone system would likely encounter stiff resistance from the physician community, as they would have to learn and operate the e-prescribing system totally apart from their existing system of ordering and recording medications. E-prescribing should be an integrated sub-system of an interoperable EHR that communicates patient data seamlessly with all other health care entities. CMS also complicates matters by proposing two

separate EHR Stark exceptions for pre- and post-interoperability certification periods. Hospitals and physicians may not want to take on the expense and work of investing in an EHR system that may ultimately have to be replaced once interoperability certification standards are finalized.

To attain its stated goal of rapid dissemination of e-prescribing and EHR technology to physicians, **CHA recommends that CMS simplify its final rule to provide for a single, unified Stark exception which would allow hospitals to give physicians integrated e-prescribing and EHR hardware, software, and related training. Further, there should only be one certification required once final interoperability standards for all HIT components are finalized. Also, CMS should not exclude from "covered technology" the ability of a donated system to perform critical administrative functions, such as patient scheduling, billing, and referrals for necessary health care services.**

- Other Technical Barriers to Donation of HIT to Physicians—Uncertainty Surrounding the Definitions of "Technically or Functionally Equivalent" and "Necessary" Items and Services.

The proposed rule creates great burdens for hospitals wishing to donate HIT to physicians, as well as recipient physicians, to assure that donated items or services not be "technically or functionally equivalent" to those already possessed or obtained by a recipient physician. The donated items or services must be "necessary," i.e., not duplicate technology and capabilities the physician already has. CMS, unfortunately, does not explicitly define "technically or functionally equivalent," other than to give a couple of examples. Also, CMS explains that its definition of "necessary" would not preclude a hospital from donating system upgrades, as long as they "significantly enhance the functionality" of the hardware/software the physician already possesses—another term CMS fails to define—leaving the donors and recipients guessing as to what constitutes compliance.

The actual burden of "certifying" that items and services being donated by a hospital are not "technically or functionally equivalent" is placed on the receiving physician. CHA does not believe that this is a reasonable burden to place upon physicians, meaning this burden will likely fall upon the donating hospitals—if, in fact, they are willing and able to perform such a complex assessment, and then take the risk that this assessment is 100 percent accurate.

The lack of certainty surrounding the above terms, and the burden on physicians of having to certify that all HIT gifts from a hospital do not in any way violate the proposed Stark exceptions, is extremely daunting for hospitals and physicians alike. As such, **CHA strongly urges CMS in its final rule to**

eliminate such a piecemeal approach to donation of HIT to physicians, which is not only technically complex, but creates compliance concerns that likely will deter such giving to occur, slowing rather than speeding the adoption of such technology. CMS must develop a much more holistic approach to allowing integrated system HIT donations to physicians, so that physicians can concentrate on serving their patients, and not worrying whether some small part of their system unwittingly violates Stark. CHA also believes that placing a cap on donated technology is premature at this point in time, and should require further CMS study, since HIT and its capabilities and costs are rapidly evolving.

- Permissible Donors and Selection of HIT Recipients

CHA believes the proposed rule's limitation of only allowing a hospital to donate HIT to members of its medical staff that routinely furnish services at the hospital is not reflective of the way care is practiced in a community, and also undermines the magnitude of patient data which can be exchanged, to the detriment of physician and patient alike. For example, there has been a significant growth in the number of hospitalists and intensivists who admit patients to a hospital, but who do not furnish services there. The hospital-based physicians who treat these referred patients would certainly have need for clinical information exchange from these admitting physicians, yet the proposed rule bars the hospitals from giving these admitting physicians the same technology. Also, many non-staff physicians refer patients to a hospital's outpatient department, and would benefit greatly if they could electronically receive test results back from the hospital for incorporation into their own patient records.

It is clear in the proposed rule that the underlying concern is that hospitals may use the free gift of HIT as an enticement to lure physicians away from other hospitals. CHA does not believe that such a gift, unless it is of extraordinary value, is, by itself, the only factor a physician considers when deciding to practice at a specific hospital. Further, CMS's overriding goal of improving patient care quality and safety by speeding widespread adoption of HIT so that hospitals and physicians are electronically connected cannot be achieved if strict rules exist about which physicians can be HIT recipients. As such, **CHA strongly urges CMS, in its final rule, to liberalize its criteria for physicians eligible for such HIT donations, to significantly increase the electronic exchange of patient information in a community, so that quality of care is optimized.**

- Lack of Regulatory Synchrony between CMS and the Office of Inspector General

As you are aware, DHHS's Office of Inspector General (OIG) released a complementary set of proposed regulations to create an Anti-Kickback statute Safe Harbor for e-prescribing technology hospital donations to physicians. Yet, OIG did not offer matching Safe Harbors for CMS's two proposed EHR exceptions. This places hospitals and physicians in a major legal quandary, since the OIG leaves the door open to interpret hospital gifts of EHR technology as a form of kickback for referring patients to a donating facility. **CHA thus urges CMS and the OIG to reach agreement on assuring that all hospital donations of HIT are covered under a single Safe Harbor, eliminating the uncertainty that now exists due to OIG's unwillingness to create a Safe Harbor for EHR donations.**

Summary

CHA believes that the many benefits that will accrue to patients and to the health care system at large, through the widespread adoption of electronic health information technology, is worthy of the massive interest and effort this goal is receiving throughout the U.S. health care sector, at both the private and public level. A recent *Health Affairs* reports shows an interoperable national HIT system would save $78 billion annually, through avoided waste, duplication, reduction of medical and medication errors, reduced morbidity and mortality—all by-products of the increased quality and productivity a national health information infrastructure would spawn.

Secretary Leavitt has stated that national EHR adoption is the "wheel that turns all others," and the proposed rules from CMS and OIG are a clear first attempt to knock down the barriers that stand in the way of this becoming a reality. However, as currently written, these proposed rules do far more to prevent rather promote this desired outcome. CHA believes that HHS must issue an unequivocal edict that puts its quality and care efficiency priorities above all else, and direct CMS and OIG to draft coordinated final rules that offer a clear, unfettered, and positively incentivized path to an interoperable HIT infrastructure that will benefit all.

CHA appreciates the opportunity to comment on CMS's proposed rule, and hopes our recommendations have been helpful.

Sincerely,

Sister Carol Keehan, DC
President and CEO

HHS Office of Inspector General
Re: OIG-405-P; Solicitation of public comment
Identifier RIN 0991-AB36

I encourage HHS Office of Inspector General to include ordering of laboratory services in the proposed Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute.

I believe inclusion of lab services ordering in the Proposed Rule will impart advantages to all U.S. healthcare providers, payers and the general public. Laboratory service provider ability to provide equipment, software to referral sources will enable:

- Automation of interactive medical necessity guideline application to diagnostic laboratory test ordering. Software that automates and simplifies complex medical necessity guidelines that apply to lab test orders serve as an educational tool for extremely busy physicians and their office staff. Since physicians and other authorized providers are not medical coders or billers they are often unaware of the various nuances of narrative indications that effect test coverage and reimbursement. The absence of interactive software that alerts physicians and their office staff that a chosen narrative does not satisfy these guidelines often results in unnecessary Advance Beneficiary Notice (ABN) administration to patients and potential refusal of patients to have such tests performed because of the belief that they will bear the costs of these tests. Absence of such ordering software also increases the likelihood of unnecessary laboratory service claims denials, increased write-offs by hospitals and laboratories or subsequent time consuming telephone calls from laboratories to physician offices to obtain different diagnostic or symptom narratives.
- More consistent administration of ABN's by requiring physician office form administration to all Medicare beneficiaries before test orders can be accepted. Physicians have little or no motivation to purchase automated software that prints these forms for non-covered lab testing when they do not perform and bill for the tests. Absence of lab-provided software and equipment that perform this function result in inconsistent and arbitrary manual ABN administration so that some beneficiaries face the difficult choice of whether or not to having lab testing done because of expensive out-of-pocket costs while other beneficiaries are not forced to make this decision simply because their physician's office staff are less diligent in administering ABN's than other offices are. When less physician office staff diligence in ABN administration is exercised it is usually the laboratory performing the testing that bears the brunt of this failure by being forced to write off the charge(s).
- Decreased lab test order errors via the availability of laboratory provider complete test menu options to the physician. Manually completed teat requisitions are often a source of test order ambiguity and performance of diagnostic testing the physician did not intend but related to the laboratory in a less than specific manner. Test order errors have been identified as a potential compliance risk by the DHHS Office of Inspector General in the 1998 OIG Compliance Program Guidance for Clinical Laboratories. While labs that strive to maintain effective compliance programs make best efforts to reduce the risk

of order errors, these risks are increased when physicians order laboratory testing using paper orders.

- Improved supply of patient Medicare Secondary Payer (MSP) information to hospitals and laboratories by physician offices. Electronic lab test ordering software that requires the provision of MSP information before a test order can be accepted can only help reduce the costs to hospitals and laboratories as well as federal and commercial healthcare program payers when instances of incorrect or incomplete MSP information is applied to healthcare claims.

While hospitals and laboratories bear the initial financial burdens due to the waste created by the problems identified above, these costs are inevitably passed on to and shared by federal and commercial payers, employers, consumers of healthcare services and the general public. In my opinion the costs incurred by these issues rival and likely surpass those laboratory-related problems identified in the preamble of the Proposed Rule.

In addition, while laboratory & hospital compliance officers understand Office of Inspector General's concerns regarding gifts of fax machines and other equipment to referral sources expressed the preamble to the Proposed Rule, the assumptions underlying these concerns are not consistent with the realities of the provision of laboratory services in more sparsely-populated rural areas. As opposed to urban markets, reference laboratories that serve rural area referral sources often receive this business because of their geographical proximity to these referral sources. Dearth of competition in these rural markets is more likely due to the fact that other reference laboratories (both large & small) view investment in these markets as disadvantageous and not because the closer laboratory provides software and equipment as a reward for referral of services.

Since both the Stark Law and OIG Fraud Alerts previously allow for the provision of "non dual purpose" items and equipment (those items and equipment used solely for test ordering and collection of specimens for testing at the lab that provides the items, equipment, etc.) I hope that Office of Inspector General considers the confusion for lab service providers that will result if software and equipment that supports these services are not included in the Safe Harbors Proposed Rule. If lab service-related software is excluded from the Proposed Rule only those labs that strive to maintain effective compliance programs will be reluctant to invest in software and equipment that will likely reduce the costs and waste associated with problems defined above because of fear that acting otherwise will be construed as abusive or as an inducement for referral of laboratory test services.

Thank you for your consideration of my concerns in this matter.

Sincerely,

Carl Faulstick
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Submitter : **Mr. Donald Fisher** **Date: 12/12/2005**

Organization : **American Medical Group Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1303-P-41-Attach-1.DOC

AMGA
American Medical Group Association

December 12, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
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7500 Security Boulevard
Baltimore, MD 21244-8010

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

Re: CMS-1301-P: Comments on Stark Physician self-referral Exceptions for EHR. Via e-mail to http://www.cms.gov/regulations/ecomments

Re: OIG-405-P: Comments of Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute Via e-mail to http://www.regulations.gov. Office of Inspector General. RIN 0991-AB36.

To Whom It May Concern:

The American Medical Group Association ("AMGA") is submitting these comments on the Centers for Medicare and Medicaid Services' ("CMS") proposed rules on "Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements," 70 Fed. Reg. 59182 (October 11, 2005) and on the Office of Inspector General ("OIG") proposed rules on Electronic Health Records, 70 Fed. Reg. 59015 (October 11, 2005).

AMGA represents physician led medical groups, including some of the nation's largest, most prestigious integrated healthcare delivery systems. AMGA advocates for the multispecialty medical group model of healthcare delivery and for the patients served by medical groups through innovation and information sharing, benchmarking, leadership development, and continuous striving to improve patient care. The members of AMGA deliver health care to more than 50 million patients in 42 states, including 15 million capitated lives.

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I. Background: What is AMGA's Interest in These Rules

AMGA's Commitment to Clinically Integrated, Coordinated Care Drives Support for EHR

AMGA's members have been at the forefront of the multispecialty practice of medicine in clinically integrated physician groups because our members believe that is the best way to deliver high quality care to patients. AMGA's members have also been at the forefront of development and adoption of e-prescribing and electronic health records systems as tools that promise to enhance the benefits of clinical integration and coordinated care for patients. AMGA embraces the Commission on Systemic Interoperability's goal of "a connected system of electronic healthcare information available to all doctors and patients whenever and wherever necessary" because it promotes quality and supports AMGA's long held belief in clinically integrated and coordinated care.[1] AMGA's members want to see robust EHR systems implemented both within our members' medical groups and in the other settings where our patients receive care.

AMGA Supports Outcomes Measurement and Pay for Performance, if well done, and Believes EHR Will Improve Quality in a Competitive Health Care Market.

AMGA also embraces the public policy in favor of measuring quality and outcomes and creating pay for performance incentives based on those measure, as long as the payment incentives include proper risk adjustment and reliable measures. Because CMS and AMGA have worked together to encourage pay for performance initiatives, we know CMS shares this concern and we will not comment further on the importance of this objective. However, we are concerned that the proposed rules can not support any pay for performance initiative because they will not encourage EHR adoption among all physicians that must cooperate to achieve desired outcomes.

EHR is developing in a competitive market that is attempting, with mixed success, to make information on quality available so that consumers -- including individual patients, employers, and health plans -- can make decisions based on quality and outcomes. In health care, quality often costs more, at least for those medical groups that are making those investments in staff and expensive EHR systems, and yet quality can enormously reduce the overall costs of health care.

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

We have heard comments from Congressional staff and OIG and CMS staff suggesting that donations of EHR may create anticompetitive "stand alone" systems or may tie donors and recipients together in a way that constitutes program or patient abuse. The experience of AMGA's membership is exactly the opposite. While some organizations are not eager to give away the value of their investments in building sophisticated EHR systems and while every EHR system is concerned about whether interfaces with other systems will introduce problems into their system, we are not aware of any medical group that is intentionally designing EHR or any component of an EHR with the objective of creating a "stand alone" system that cannot communicate with other systems. Medical groups recognize that interoperability is both coming and is desirable for the physicians, clinicians, health care facilities, and patients who are the most important users of the systems. Competition will drive both EHR adoption, as EHR is increasingly recognized as an essential tool for practicing high quality medicine, and it will drive interoperability because the ultimate consumers and users will demand that.

AMGA Urges CMS and OIG to Use These Rules to Facilitate Steps in EHR Adoption

In our experience, medical groups are taking the following steps that support the goal of EHR that connects physicians and patients whenever and wherever necessary.

1. Implementing EHR within the group and providing physicians in the group access to the EHR wherever the group's physicians provide care.[2]
2. Providing access to the information in medical groups' records to outside physicians and other clinicians who also treat these patients and use our physicians as consultants.
3. Creating a "patient portal." While groups must approach electronic communications with these patients cautiously, many have developed a patient portal, giving patients access to limited clinical information and reminders, and are convinced that electronic communications with patients will develop over time as a powerful tool for improving patient care.
4. Gaining electronic access to information on medical group patients held in the electronic record systems of other providers and health care facilities.
5. Implicit in 4 is encouraging outside physicians and other health care organizations, with whom medical groups share patients, to move their own records into an electronic format that would then be accessible to our physicians and eventually interoperable with the medical group's EHR.

[2] Physicians in medical groups provide care in hospitals, nursing homes, and outreach clinics, for instance. Once they understand the power of the EHR as a clinical tool in their practice, they insist that they have it available wherever and whenever they see patients. Most systems provide access through passwords, and the groups work with outside providers to be able to use the computers in other settings to gain password access. In some cases, the groups have placed compatible hardware, solely for use by members of the group or by other clinicians with legitimate password access, in these outside facilities so they can gain access to the group's EHR while taking care of patients in these other settings.

None of these steps, once taken, is easily sustained or maintained. Each involves new work patterns, privacy and security measures, constant system training and retraining, enormous technical support, and constant updates and upgrades to the technology.

Many medical groups have already taken that first step. The Stark law and AKS do not present a barrier to groups developing their own EHR systems. Many have also taken the second step of giving outside physicians "read only" access to information because they do not believe that doing so is remuneration. It simply replaces faxed and mailed patient records from the group's medical records department with password access (and necessary training and privacy and security measures) into our group's EHR systems. Although complex to implement, many of AMGA's groups have taken the third step and have built patient portals to communicate with patients and to allow patients access to some part of their own medical information in the group's EHR systems.

Steps 4 and 5 are more difficult. Step 4, gaining access to another EHR system, can be done at the individual level by giving physicians a password into another system, in the same way our groups frequently provide outside physicians with access into our EHR systems. Giving a physician a password will sometimes trigger a fee. Because of HIPAA security rules, passwords must be given to every individual user, which means that for an entire medical group to gain access into another system's EHR, many passwords are involved and possibly the payment of many fees. Because we do not believe it would be remuneration for those fees to be paid by either side of this relationship, we do not believe this requires special protection under these rules. However, CMS and OIG should state that this is not remuneration. The other way to gain access into another system is for systems to be interoperable or connected through a health information network, where any physician with a password can access information on his or her patients in the interoperable system or health information network. This is still largely in the future, although we hope the not too distant future. This step requires that all physicians and other health care providers put their information into electronic format, that those EHR systems be constantly upgraded to meet evolving interoperability standards (which will require both upgrades to software and related technical support), and that an infrastructure is created to maintain the system and address privacy and security requirements. CMS and OIG need to allow the full range of donations to facilitate the transition to an interoperable EHR.

Step 5 – encouraging all health care providers to transition from paper to electronic records – is likely to be accomplished in two ways. First, CMS and OIG need to clarify "remuneration" and "fair market value" in the context of EHR, discussed below, so medical groups can explore the possibility of "selling" EHR to outside physicians under existing law. Second, CMS and OIG need to make it possible for donations to be made by medical groups to encourage outside physicians and other providers to move down the road to having electronic records in their own offices. CMS and OIG also need to make it possible for medical groups to receive donations from other entities.

How Medical Groups Are Affected by These Rules

Because AMGA's members are further along in adopting EHR than many physicians, they are ready to actively encourage adoption of EHR outside of their groups and connectivity between their own EHRs and other EHR systems. In that way, medical groups are affected as donors. In fact, medical groups that have EHRs are frustrated by the fact that other physicians and providers are still using paper, mail, fax, and phone to communicate and do not have the kind of clinical decision support increasingly viewed as necessary to care for patients well. Many groups feel the need to encourage EHR adoption because, once a medical group has implemented an EHR, it becomes increasingly difficult to work with providers that use a paper-based system. AMGA's members are also affected as potential donors because we work with other systems to facilitate our ability to connect our EHR systems with theirs.

In other words, AMGA's members respectfully request that CMS and OIG help them take steps 4 and 5 above. AMGA's member medical groups can advance EHR adoption both as donors and as recipients under the proposed rules. AMGA will comment, therefore, from both perspectives.

CMS and OIG should understand that AMGA's members include not only "group practices" as that term is defined in the Stark laws, but medical groups that do not fall within that definition because they are part of larger systems or because they are highly integrated independent practice associations (IPAs) of physicians who continue to maintain practices outside of the medical group. AMGA, therefore, view the proposed rules from the perspective of physicians in clinically integrated organizations that have embraced the promise of EHR for improving patient care, not just as "group practices" under Stark.

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

Encouraging EHR adoption is not only about encouraging donations under these rules. Many of our members do not intend to donate EHR technology, training, or technical support to outside physicians or other health care entities. However, some would like to sell or make available EHR office software systems to outside physicians.[3] Some would like to offer the services of their information technology technical support staff to help outside physicians and other organizations evaluate their EHR options or to diagnose problems in connecting different EHR systems.

For these medical groups, CMS and OIG could encourage the spread of EHR by distinguishing what they believe is and is not remuneration, within the context of EHR

[3] Medical groups can donate software either as vendors of their own proprietary systems or because they have contracts with their EHR vendors that allow the group to make EHR available to outside physicians under a "users" agreement or sublicense.

development and adoption. Further, it is important that CMS and OIG clarify how to determine the "fair market value" of providing EHR technology or services. This should include making it clear that establishing price on the basis of the direct, incremental costs of the medical group making EHR technology or related services available is considered fair market value.

Some groups would also be interested in acquiring EHR systems (either for the first time or as a replacement of an existing system) from other groups or from hospital systems. They would often prefer working with such closely related health care organizations on EHR development. One of the barriers to EHR development has been the difficulty some groups face in finding reliable, well-tested EHR systems at a reasonable price. If these groups could purchase EHR technology and services from other health care organizations at a reasonable price, they would do so. CMS and OIG could help by making it clear that passing through the direct, incremental costs of providing the services, or any other reasonable method of pricing, will satisfy the fair market value standard in both the Stark law and AKS.

III. E-Prescribing Rule

This comment will not address the proposed e-prescribing rule in detail. While we strongly support e-prescribing as a valuable function of an EHR system, we believe it is only fully effective when integrated into an EHR clinical information system. We do not believe that e-prescribing systems as stand alone systems are best for patient care. As written, the e-prescribing rule -- because of the restrictiveness of the "necessary and used solely language," as well as the limits on donors and recipients -- is not likely to be helpful for promotion of either e-prescribing donations or for building a distinct e-prescribing package that could be integrated with an EHR platform.

We do not believe the e-prescribing rule can be fixed given the constraints from the Medicare Modernization Act of 2003.[4] Rather than recommend ways to modify the e-prescribing rule, we believe that CMS and OIG should recognize that e-prescribing separate from EHR is not likely to be accepted in the current health care marketplace, except in niche areas that are not very effective at promoting the overall objective of rapid and widespread adoption of EHR. Therefore, most donations under the proposed rules are likely to occur because of the EHR exceptions and safe harbors, and not because of the e-prescribing rules.

Our main comment on the e-prescribing rule is, therefore, to urge CMS and OIG not to carry the limitations in the e-prescribing statute and rules into the EHR rules. We support CMS's and OIG's intention to exercise their separate rule making authority, entirely apart

[4] Based upon our conversations on Capitol Hill, we believe if Congress had understood how the "necessary and used solely" language and the limitations on donors and recipients would undermine the ability to integrate e-prescribing into clinical information systems, it would not have used that language.

from the e-prescribing authority given by the Medicare Modernization Act, to create exceptions and safe harbors to promote rapid adoption of EHR, imposing only those conditions and limitations necessary to prevent patient and program abuse.

IV. EHR Exceptions and Safe Harbors

AMGA supports the comments submitted to OIG and CMS by Coppersmith, Gordon, Schermer, Owens, and Nelson ("Coppersmith Gordon") on behalf of a number of health care organizations, including several AMGA members. Those comments are attached to this comment, and should be regarded as part of AMGA's comment. In particular, we support the following changes in both the pre-interoperability rules and the post-interoperability rules.

1. Covered Technology and Services

We support a broad definition of "electronic health record," including the ability to track patients' care over time, computerized provider order entry, clinical decision support, and e-prescribing. Policy reports on EHR as well as government pay for performance initiatives have also identified functions and outcomes expected of EHR systems to support quality and pay for performance initiatives. CMS and OIG should deem that donations designed to substantially further those functions and outcomes fall within the definition of EHR.

OIG and CMS should also recognize that the EHR should be used to support quality improvement by monitoring clinician compliance with protocols and utilization guidelines. EHR also allows monitoring of activities that support pay for performance objectives. These functions should be explicitly recognized as protected by the definition of EHR.

The lack of technical support for EHR adoption is a major reason that physicians in smaller practices have been slow adopters.[5] In contrast to small physician practices, many of AMGA's groups have sophisticated information technology support staff. Few changes in the rules would be more useful in spurring EHR adoption than allowing donations of technical support. We want to emphasize, however, that AMGA's groups would also benefit from being able to accept donations of technical support from other organizations, as we work to evaluate our ability to integrate our EHR systems with theirs, and to consider placing components of their EHR into our own systems. We expect that a give and take will and should occur around EHR development, and that donations of both software and technical support, would enhance innovation. CMS and OIG should add protection of technical support at all stages of EHR development in the final rules. This should extend to interface support between the EHR software and

[5] See Office of National Coordinator at ; MedPAC March 2005 Report to Congress, at ; and 2005 Commission on Systemic Interoperability Report.

administrative systems. Organizations should be allowed to donate technical support to evaluate EHR software in any physician's office or health care entity with which they have a patient care relationship.

CMS should allow donations that are "used in connection with" EHR functions, rather than the more restrictive language requiring donations to be "necessary" to EHR functions. This achieves CMS's and OIG's objective of preventing donations that have some value to recipients separate from support of EHR, without requiring donors to determine if software they are donating may be "technically and functionally" equivalent to software physicians and other entities currently possess. That determination is practically unrealistic, especially given the complexity of the software, constant updates and upgrades, and the fact that donors will often grant recipients the ability to use, for their own practices, the EHR system used by the donor. In those instances, the donor is not able to readily tailor the donation to each possible recipient. Furthermore, many groups that acquired first generation EHR are now ready to move to better systems. They would like to be able to accept donations of technical support and perhaps other donations of software as they replace their current systems with ones they acquire from donor systems that have updated their systems. The word "necessary," and the related certification requirements, enormously complicate what should be a simple process of replacing one EHR system with a better one.

2. Permissible Donors

The proposed rules specifically limit potential donors to those identified in the Medicare Modernization Act. We see no reason to carry this limitation into the EHR rules. Indeed, given the objective of connecting "all doctors and patients whenever and wherever necessary," we urge CMS and OIG to define potential permissible donors as broadly as allowed under their respective jurisdictions.

CMS and OIG limit group practices to making donations to their own employees or members. As CMS and OIG know, group practices can provide EHR to their own employees and members under existing law. As written, these rules provide no additional protection to group practices in that regard.

The OIG has asked how group practices can also provide EHR to independent contractors working for the group. 70 Fed. Reg. at 59019. Group practices can provide EHR to independent contractors (or employees or anyone else) for use in taking care of the group's patients or for conducting other aspects of group operations because doing so cannot possibly be considered remuneration. Providing EHR to physicians who are acting as physicians of the group, whether as employees or independent contractors, is no more remuneration than providing office space, a medical records department, or good nursing staff. One reason that group practices have been early adopters of EHR is because existing law does not inhibit group practices from making EHR available to their

own physician staff.[6] We are concerned that OIG, by its request in the proposed rules with regard to independent contractors, may have created confusion around this very basic point, and would request that OIG make it clear that it is not remuneration for group practices to provide EHR support to any physician acting on the group's behalf, whether as a member, employee, or independent contractor.[7]

Some of AMGA's members would not be permissible donors under this narrow definition of a "group practice." We are particularly concerned that the final rules allow networks of physicians (which will often include medical groups) to be both donors and recipients of EHR. Primary donors should be allowed to use related organizations, such as a management services organization (MSO) or independent practice association (IPA) (which will often be part of an integrated delivery system (IDS) that includes the donor), as an intermediate donor for channeling donations to physicians or other entities that are legitimate potential recipients. Donations by a donor that bills Medicare to an IDS, IPA, or MSO would otherwise trigger scrutiny as indirect compensation arrangements under existing law. For instance, a hospital system may have created a separate MSO to manage the billing, personnel, and information technology needs of physicians or medical groups. The physicians and medical groups affiliated through this MSO, IPA, or IDS will often also contract as a network with payors and, therefore, work together to achieve pay for performance objectives which require a common EHR.[8] The MSO, IPA, or IDS is, therefore, an appropriate vehicle for channeling EHR donations from the hospital to physicians and medical groups.

As long as the permissible donors have a patient care relationship with permissible recipients and otherwise comply with the other conditions in the rules, we see no reasonable potential for patient or program abuse as the result of a broad definition of permissible donors.

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[6] Medical groups have economies of scale that smaller physician organizations can not achieve on their own. They can achieve similar economies of scale through networks (IPAs, MSOs, or IDSs). They can also take advantage of the price negotiated by a larger provider organization from whom they purchase EHR, perhaps at a subsidized price if these rules allow.

[7] We understand that providing EHR for the outside office practice of an independent contractor would raise concerns under the Stark and AKS, and would need to fall within an exception.

[8] IPAs will not directly bill Medicare in many cases, and, therefore, will only be affected by Stark law and AKS because of indirect compensation arrangements with donors that are subject to those laws. It is, however, important that IPAs and MSOs, when they receive EHR support from a related health care organization that bills Medicare, are allowed to make donations to the practices of the physicians they manage. IPAs and MSOs have been at the forefront of pay for performance contracting in markets. In order to be able to negotiate fee-for-service contracts, they must be clinically integrated according to the legal standards established under the antitrust laws. A common EHR is an essential tool in allowing the level of clinical integration within IPAs and other kinds of physician networks that is required by the antitrust laws to allow for such price negotiations (except to the extent that such price negotiations create financial integration). See FTC and Department of Justice, Improving Health Care: A Dose of Competition, July 2004.

3. Permissible Recipients and Selection of Recipients

Assuming that CMS and OIG have embraced the objectives of interoperability and of encouraging connections between physicians and patients whenever and wherever necessary, the final EHR rules should allow donations to any physician or other health care entity that is involved in shared treatment of patients. As written, the proposed rules make it impossible for medical groups to encourage EHR adoption by donations to physicians who are not members of the group but who regularly share patients with the group.

Broadening permissible recipients is perhaps the single most important change in the proposed rules to further the goal of rapid adoption of EHR to connect physicians in all practice settings. Many of AMGA's members provide subspecialty care in large geographic regions. Often the physicians who send patients to medical groups are in rural areas, where we know that EHR adoption has been especially slow. However, whether in a rural or urban area, our members work with physicians who are on the medical staffs of hospitals which have not yet implemented an EHR system and are in no position to encourage EHR adoption by members of the medical staff. These physicians often lack the ability to engage in the selection of an EHR system, to negotiate the contract, and to implement and maintain an EHR, without help. It is natural for them to turn for help to the larger health care organizations, including the large multispecialty medical groups that are members of AMGA, with whom they regularly share patients. These outside physicians and other providers already trust us and can see the benefits of an EHR for management of shared patients because they have seen the benefits of our EHR systems in management of their patients. These outside physicians are not medical group employees, nor are they on the medical staff of the hospitals where our physicians practice. Whether in rural or urban areas, these are the most important potential recipients who need to be addressed in the final EHR rule.

AMGA's members are also frequently medical directors of nursing homes. The residents in nursing homes and in other post acute settings are often medically complex, use a number of different medications, and have chronic diseases that would benefit from management according to a clinical protocol over time. Not allowing EHR donations to the settings in which these patients reside and receive most of their care is another fundamental flaw in the proposed AKS safe harbors.

AMGA fully supports the recommendations related to interpretation of the "volume or value" language in the proposed post-interoperability rule in the comment submitted by Coppersmith Gordon. We believe it is important to "deem" that medical groups can focus their EHR donations to permissible recipients based on the historical fact of shared patients, a concern for treatment of shared patients with a disease or medical concern that would benefit from a clinical protocol build into an EHR, shared need to achieve outcomes measures in a pay for performance initiative, and support of safety net providers.

The crucial factor in allowing a donation should be a historical relationship between the donor and recipient around the shared care of patients. CMS and OIG should not, however, try to establish a minimum number of shared patients. As long as the group establishes legitimate criteria for identifying permissible recipients, without regard to the volume or value of referrals, CMS and OIG should respect that determination.

4. Value of Protected Technology and Other Conditions

Medical groups share with other potential donors and recipients the concerns expressed in the Coppersmith Gordon comment with the cap and with other conditions that will be difficult and expensive to implement and do not truly address realistic concerns with patient or program abuse.

In particular, AMGA emphasizes the importance of not allowing these rules to inhibit innovation in the future development of EHR. Our members are improving their EHR systems everyday. They are painfully aware that CMS and OIG could squelch innovation unintentionally by documentation, certification, and valuation requirements that do not realistically address the rapid and constant developments in EHR products and markets right now. They are especially concerned about the documentation, certification, and valuation requirements under the Stark law, which carries substantial penalties for even harmless, unintentional mistakes.

AMGA is therefore especially supportive of not imposing documentation, certification, and valuation requirements under the Stark law. While we hope that CMS and OIG will abandon some of the requirements they have proposed because they do not realistically address program or patient abuse and may stymie innovation, if CMS and OIG carry certain elements of these requirements into the final rules, they should do so through the AKS safe harbors, and not the Stark exceptions (except by incorporation of the AKS).

V. The Pre-Interoperability Rule

As the pre-interoperability rules are currently proposed, we do not expect our members to donate until the post-interoperability rules are finalized. The increased risks of donation under the pre-interoperability rule, as described in the Coppersmith Gordon comment, are likely to result in a "wait and see" approach.

We support the prohibition on actions to unnecessarily restrict or limit the use or compatibility of donated software with other systems as proposed in § 411.357(w)(2). Other than that, we also do not believe that the differences between the pre-interoperability rule and the post-interoperability rule can be justified in terms of a concern with patient or program abuse, although we would support conditions in the pre-

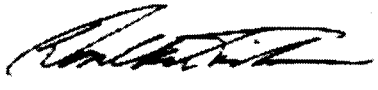
interoperability rule that facilitate the transition to EHR systems that comply with interoperability standards once finalized.[9]

CMS and OIG should not use these rules to try to leverage interoperability. We do not see how doing so is within CMS's and OIG's authority to address program and patient abuse. But, even more fundamentally, CMS and OIG do not need to use these rules to leverage interoperability. We are concerned that CMS and OIG underestimate how aggressively the market is moving toward interoperability and toward electronic connections between providers even in the absence of accepted technical standards of interoperability. We believe that CMS, by drafting overly narrow pre-interoperability rules, will unintentionally prevent donations that encourage EHR adoption, and will do so even though there is no risk of program or patient abuse given the conditions suggested in this comment and the Coppersmith Gordon comment. Unless the pre-interoperability rules are revised along the lines suggested, we are concerned that CMS and OIG will create a situation where records that are in paper stay in paper until the post-interoperability rules are finalized.

VI. Conclusion

AMGA and its members have a very long track record of support of EHR systems. We appreciate the difficulty of the task faced by CMS and OIG. EHR systems are very complex. Drafting useful rules requires understanding EHR markets and products, current contracting practices, barriers to EHR adoption, and the operational implications of adopting EHR systems, among other issues. If CMS or OIG would like AMGA members to help them understand and address these issues, please contact us.

Sincerely,



Donald W. Fisher, Ph.D.
President and CEO
American Medical Group Association

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[9] While we believe such transitional provisions are not necessary, because the market will push in that direction more effectively than this rule, we also do not believe such transitional provisions would further delay EHR adoption under the pre-interoperability rule.

AMGA wishes to acknowledge Kathy Kenyon at Kenyon Law Firm who assisted in preparation of this comment.

Coppersmith Gordon Schermer Owens & Nelson PLC
Attorneys and Counselors

December 12, 2005

Delivery via: http://www.regulations.gov, Office of Inspector General, RIN 0991-AB36

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

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

To Whom It May Concern:

We are writing on behalf of health care organizations committed to electronic health record (EHR) systems designed to improve quality and facilitate "a connected system of electronic healthcare information available to all doctors and patients whenever and wherever necessary."[10] The health care organizations sponsoring this comment are: Banner Health, Billings Clinic, The Cleveland Clinic Foundation, Intermountain Health Care, Partners HealthCare System, Inc., Scottsdale Healthcare Hospitals, and St. Joseph's Hospital.

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

The Stark physician self-referral exceptions and the anti-kickback safe harbors differ in two ways that are important to this comment. First, the AKS safe harbors apply to a much broader range of potential permissible recipients of EHR donations. Second, the

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

AKS safe harbors are not mandatory and, therefore, allow for enforcement discretion not to pursue conduct outside of the safe harbor. Furthermore, the availability of individual case-by-case advisory opinions under the AKS gives potential donors a way of seeking comfort that a business strategy they believe benefits patients, but may be perceived by some as intended to induce referrals, is legally acceptable. The implications of these differences for the AKS safe harbors are discussed below.

Permissible Recipients

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

In particular, patients in post-acute facilities and settings, who often have complex medical conditions involving multiple prescriptions, should have their records available in an electronic format and subject to the clinical protocols and alerts built into EHR systems.[11] Health care organizations, including the sponsors of this comment, often provide physician medical direction to nursing homes. Those medical directors are frustrated about the lack of EHR in nursing homes. The slow rate of adoption of EHR in nursing homes[12] (less than 5%, according to MedPAC) increases the likelihood of errors for some of the most disabled patients, with long term chronic conditions, who are often cared for by a large number of different physicians and other providers. Diabetes is also common among residents of nursing homes. The failure to implement EHR in these settings means that it is much more difficult to know if diabetic care is being managed according to clinical protocols built into the EHR. The health care organizations that provide physician medical directors should be allowed to target donations to nursing facilities that care for the same patients.

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

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

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

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

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

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

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

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

Conclusion

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

Sincerely,

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December 12, 2005

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

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

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

To Whom It May Concern:

This letter provides comments on the Centers for Medicare and Medicaid Services' ("CMS") proposed rules on "Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements," 70 Fed. Reg. 59182 (October 11, 2005). We are writing on behalf of health care organizations committed to the implementation of electronic health record (EHR) systems to improve quality and facilitate "a connected system of electronic healthcare information available to all doctors and patients whenever and wherever necessary."[13] The health care organizations sponsoring this comment are Banner Health, Billings Clinic, The Cleveland Clinic Foundation, Intermountain Health Care, Partners HealthCare System, Inc., Scottsdale Healthcare Hospitals, and St. Joseph's Hospital and Medical Center. The American Medical Group Association also supports this comment.

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

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

geographic markets from Boston to Billings, serving all kinds of patients, providing all levels of medical services.

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

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

We know that CMS and OIG are aware of the huge benefits of EHR system adoption and support the goal of removing unnecessarily restrictive regulatory impediments to EHR adoption.[14] We also recognize CMS's statutory obligation not to create exceptions that allow for patient or program abuse. We therefore believe CMS should write more expansive exceptions with the goal of encouraging EHR system adoption, but with conditions or other limitations necessary to prevent patient or program abuse.

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

[14] 2005 Commission on Systemic Interoperability Report at 2; MedPAC, March 2005 Report to Congress at 219.

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

The sponsors of this comment want to encourage adoption of EHR systems by physicians on their hospital medical staffs and by physicians who are not on their medical staffs but who share patients with their employed physicians or with physicians on the medical staff. However, with few exceptions, the sponsors are not interested in donating the full value of an EHR system. First, they want outside physicians to be able to access the information in the sponsor's EHR on care received at the sponsor by the outside physicians' patients. For physicians who are on the sponsoring organization's medical staff, this access would include the ability to use the sponsoring organization's EHR for care of the physicians' patients while in the hospital.[15] Second, the sponsors of this comment want to make it possible for these outside physicians to create their own office practice EHR for their own patients (which would in turn be accessible by a hospital that also treats that patient) by becoming "users" of or sublicensing the sponsor's EHR systems at the direct, incremental costs to the sponsor.

The sponsors of this comment already have taken the first step toward giving outside physicians access to information on their patients within the sponsors' EHR systems. Based in part upon previous CMS guidance, they do not believe that giving "read only" access to physicians is "remuneration;" nor do they believe that allowing physicians on their medical staffs "read and write" access to order tests and medications or to view and enter additional information into patient records (even from their offices) is remuneration.[16] While these widely shared assumptions have allowed the expansion of the use of EHR, CMS should state clearly that read and write access to a hospital EHR system is not remuneration. In addition, CMS should state that it is not remuneration to

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

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

give physicians access to clinical protocols and electronic medical libraries,[17] even if doing so provides an incidental benefit to the physicians' patients who are not shared.[18]

Second, the sponsors of this comment want to allow outside physicians to take advantage of the pricing the sponsors can make available at their direct, incremental costs for EHR technology and support services, which would enable the outside physicians to create their own office EHR for their own patients. In our experience, a common practice is for larger health care organizations to function as purchasers of EHR systems for smaller "users,"[19] with the EHR vendors knowing that the larger health care organizations will pass through the direct, incremental costs of providing an office practice EHR for the outside physician practices as the "fair market value" price.[20] 42 U.S.C. §1395nn(e)(8) permits the provision of items and services to physicians "at a price that is consistent with fair market value." CMS should clarify that the "fair market value" standard is satisfied when larger health care organizations price EHR systems, components of systems, or technical support services for additional users, including outside physicians and their practices, on the basis of the organization's direct, incremental costs. *See* 42 U.S.C. § 1395nn(h); 42 C.F.R. § 1001.952. This, in and of itself, will make a substantial contribution to the ability of larger health care organizations to encourage adoption of EHR systems by physicians in small practices.

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

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

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

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

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

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

A. Covered Technology

It is vitally important that any new rule provide for a broad definition of electronic health records and a wide array of uses of electronic health record systems. The proposed EHR rule language is too narrow to encourage the known benefits of EHR adoption in physician offices as characterized by the Commission on Systemic Interoperability, Institute of Medicine, and the Medicare Payment Advisory Commission (MedPAC).[21] The proposed rule limits protection to "[n]on-monetary remuneration (consisting of items and services in the form of software or directly related training services) necessary to receive, transmit, and maintain electronic health records" under specified conditions.

1. Adopt a Broad Definition of the Protected EHR System

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

CMS has asked for comments on the definition of "electronic health records." 70 Fed. Reg. at 59188. We believe the definition should be designed to accomplish at least two well-established objectives of EHR systems.[22] First, it should promote "a connected system of electronic healthcare information available to all doctors and patients whenever and wherever necessary."[23] Full information exchange among providers reduces errors and improves quality. Second, EHR systems should be a tool for collection of quality and outcomes measures to facilitate pay-for-performance payment methodologies. CMS is a major proponent of such measures, so we will not describe them further in this comment.

In discussing "covered technology," CMS has expressed its intent to protect "integrated packages that could positively impact patient care," while avoiding protection

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[21] 2005 Commission on Systemic Interoperability, supra; Institute of Medicine, *Crossing the Quality Chasm* (2001) and *Quality Through Collaboration: The Future of Rural Health* (November 2004); MedPAC, March 2005 Report to Congress, Chapter 4, "Strategies to improve care: Pay for performance and information technology. See also research on how EHR is actually used in small physician offices. R. Miller, et al, "The Value of Electronic Health Records in Solo or Small Group Practices," 24 Health Affairs 1127 (September/October 2005).

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

[23] 2005 Commission on Systemic Interoperability Report, at 11 Executive Summary. See also MedPAC, March 2005 Report to Congress.

of administrative software that does not also further the goal of improving patient care. 70 Fed. Reg. 59188 and 59190. Consistent with CMS's intention, MedPAC in its March 2005 Report to Congress explicitly embraced EHR as a valuable tool in achieving the two objectives above – promoting connectivity to achieve quality and measuring outcomes – and made a distinction between EHR clinical information technology systems and other "administrative systems." MedPAC describes an EHR "clinical information technology" (IT) system as follows:

> Clinical IT comprises multiple applications that support different functions in health care, such as:
> - tracking patients' care over time (the electronic health record);
> - allowing physicians to order medications, lab work, and other tests electronically, and then access test results (computerized provider order entry);
> - providing alerts and reminders for physicians (clinical decision support systems); and
> - producing and transmitting prescriptions electronically (e-prescribing).[24]

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

MedPAC also discusses specific "functions" and "outcomes" of clinical information technology, especially important for allowing measures of quality and outcomes. The "functions" include: registry for patients with chronic conditions; registry for all patients; system for tracking patients after an acute event to determine follow-up; system for tracking test results and prompting follow-up of abnormal tests; medication safety checks (allergies, dose, age, drug-to-drug interactions); system for decision support within the patient encounter; system for tracking lab results, including status of patient notification; and system for aggregating, measuring, and monitoring patients by category, such as disease, medications or age.[25] The "outcomes" of clinical information technology identified by MedPAC include: patients with chronic conditions tracked and sent reminders prompting office visits or other necessary follow-up; patients in the practice screened for risk factors; patients who are identified as at-risk are contacted; patients with potential drug-to-drug interactions are contacted; patients are contacted to communicate lab results; and quality measured internally and care management improved.[26]

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[24] MedPAC 2005 Report to Congress at 206.
[25] MedPAC 2005 Report to Congress at 198.
[26] MedPAC 2005 Report to Congress at 198.

We recommend that the definition of EHR used in the CMS exception be at least as encompassing as the MedPAC definition of clinical information technology, and that CMS articulate a presumption that software falls into the protected definition of EHR if it is designed, marketed, or reasonably used in a way that substantially fits any element of that definition. Further, CMS should state that software designed primarily to further the functions and outcomes of EHR described by MedPAC (or other similar functions and outcomes as the technology develops) is deemed to meet the definition of protected EHR.

If the "outcomes" MedPAC identified above are deemed to fall into the definition of EHR, a "patient portal" that includes communicating with patients about the full range of clinical issues, such as scheduling, appointment reminders, and alerts, will be protected. In addition, as the Commission on Systemic Interoperability has pointed out, the ability of patients to electronically access their own EHR information, such as results of lab tests, will become increasingly important to improving patient care. Patient portal software is designed to facilitate a broad range of patient communications. Therefore, we recommend that CMS include patient portal software, including a scheduling function, in the definition of protected EHR.[27]

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

CMS should not require that a donation have all of the elements CMS regards as "core" to an EHR. For instance, the organizations sponsoring this comment strongly believe in computerized provider order entry (CPOE), and believe it must be included in any definition of a protected EHR system; however, we do not believe that donations should be *required* to include CPOE to be protected. Similarly, while we strongly believe that providing access to an electronic medical library should fall into the definition of a protected EHR system because it is part of clinical decision support,[28] we would certainly not argue that it must be included in order for the donation to be protected, although we believe donors should be allowed to donate it as an addition to an existing EHR system. Trying to force broader EHR system adoption by only protecting EHR donations that include defined "core" elements is likely to have the unintended consequence of discouraging donations of important components of a system.

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

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

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

2. Include Technical Support

One major reason for slow EHR adoption by physicians is lack of available technical support to acquire and maintain an EHR system.[29] Painful and expensive experience with installation of software over the past decade has demonstrated that reliable technical support is essential to successful implementation and ongoing maintenance of any software system. All of the sponsors of this letter have built substantial internal IT support services. None of the sponsors of this comment would have considered implementing an EHR system without having in place both reliable internal technical support (often called the "help desk') to address routine questions and diagnose problems, as well as outside technical support to solve problems internal IT staff cannot solve and to provide ongoing updates and upgrades to the system.

As a practical matter, EHR software must interface with administrative software, and technical support will be required to make those interfaces work. Organizations that adopt EHR systems will have previously begun the journey toward electronic systems with some kind of administrative software (given Medicare requirements, they probably

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

started with electronic billing software), and that software will need to interface with the EHR software.[30] To avoid repeated collection of demographic and payor information from patients, interfaces with the billing and practice management software must be developed. Coding software, designed to support coding and reduce mistakes, also should interface with EHR software.[31]

Donations of technical support should be protected, even if not accompanied by donations of EHR software, as long as the technical support is connected to the acquisition or use of an EHR system. This will reduce the likelihood of program abuse by allowing donations of EHR technical support to physicians who want to evaluate how an existing EHR system can better communicate with other EHR systems. For instance, if a physician received some of his EHR system from one vendor or donor and wants to know how it can be made to communicate with another system, the other system should be able to donate technical support to make that assessment. Doing so will promote interoperability and connectedness, and reduce the ability of any single donor of EHR to work exclusively with a physician. Donations of technical support will also promote connecting different EHR systems into community health information networks, as they develop. Furthermore, the Department has made the EHR software used by the Veteran's Administration, VistA, available to all physicians, for free. Physicians in small practices may find this attractive, but only if they receive technical support to evaluate the appropriateness of the software for their practices, to install it, and to maintain it over time. Donors should be allowed to donate technical support of EHR software, including interfaces to administrative software and connections to other EHR systems, even when they do not donate that software themselves.[32] Without such protection, many EHR systems will not be properly installed or maintained in physicians' offices, both negating the benefits of the system and souring many physicians' perceptions of the benefits of EHR.

We therefore urge CMS to write an exception that allows donations of technical support at all stages of EHR acquisition, implementation, and maintenance, including support of the interfaces to related administrative software and connections between EHR systems. Furthermore, as discussed below, because of the difficulty of valuing technical support and because such donations will not lead to program abuse under the conditions

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

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

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

recommended in this comment, we recommend that it be removed from any cap CMS might consider and from any obligation to "value" donated EHR-related services.

3. Remove the Requirement that Donations Be "Necessary"

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

In the context of the EHR exception, which, if the recommendations in this comment were adopted, would apply only to EHR software, training, and technical support, there is no hardware equivalent to which the term "necessary" would apply. We do not know of a reasonable way to evaluate whether software, training and technical support is "necessary" or "technically or functionally equivalent" to anything the recipient possesses.[33] Would this require a donor to determine, for each and every potential recipient, if a higher quality EHR related donation is really "necessary" if a lower quality one might do? When a requirement is difficult to determine and carries substantial penalties for mistakes, lawyers will recommend hiring expensive outside experts,[34] diverting scarce resources from beneficial EHR donations and into documentation and certification efforts. Indeed, the potential for confusion, uncertainty, and perceived legal risk may be higher in this section than any other in the proposed rule. Moreover, we fail to see how either the word "necessary" or the related certification requirement prevents program abuse, as long as the donation is connected to legitimate EHR functions.

Dropping the word "necessary" from the language of this section would break the connection to the e-prescribing rule's use of the term and to the certification requirement that donated technology not be "technically or functionally equivalent" to what the physician possesses at the time of the donation. We recommend replacing "necessary" with the less restrictive phrase "used in connection with."[35] It would also eliminate the need to determine if donated EHR software is "necessary" if free software, such as the

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

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

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

VistA software, is "technically and functionally equivalent." The "used in connection with" language sufficiently limits the donation to EHR functionality, without allowing donations that support other aspects of a physician's professional or personal activities.

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

In many cases donors will make EHR systems available to outside physicians by paying a user's fee or licensing fee to the vendor of the donor's EHR system, in accordance with the contract between the donor and the EHR vendor. CMS needs to make it clear that this payment, because it is necessary to the donation of the EHR, is protected by the CMS EHR exception. CMS also needs to make it clear that the outside physician and the donor system can split this fee (on some basis unrelated to the volume or value of referrals), which would effectively allow the donor to subsidize the physician's acquisition of the EHR system, without covering the full costs. Furthermore, consistent with the discussion below of permissible recipients, the donor system should be allowed to give all of the physicians in a targeted physician's group, employer, or network (who tend to share coverage and call) the ability to be added as users by payment of the user's fee or license fee, whether or not the donor chooses to subsidize some part of the fee.[36]

B. Permissible Donors

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

CMS should explicitly allow a donor "entity" subject to Stark to use a separate, but related organization, such as a Management Services Organization (MSO) or an independent practice association (IPA), as a vehicle for donations protected by this rule.[37] In addition, there is no reason to exclude post-acute facilities (nursing homes and home health agencies), laboratories or ambulatory surgery centers, each of which may have a special component of an EHR that may be especially useful in improving patient care in their area of expertise, as long as the donation is related to care of shared patients. Indeed, allowing more potential donors may actually **reduce** the risk of program abuse.

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

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

C. Permissible Recipients and the Selection of Recipients

As currently written, the rules allow hospitals to donate only to members of the medical staff who "routinely furnish services at the hospital,"[38] group practices to give to their own employees and members, and prescription drug plan (PDP) sponsors and Medicare Advantage (MA) organizations to give to physicians. On this point the rule is unnecessarily narrow and fundamentally contrary to the goal of connecting all physicians and other providers to health care information whenever and wherever needed.

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

As potential hospital donors, we believe limiting permissible recipients to members of the medical staff is far too narrow and will leave many of the patients we serve without a way of including all of their health information into an interoperable EHR. All of the sponsors of this comment have a large number of employed physicians or physicians on the medical staff who regularly provide consulting and care to patients who use physicians who are not on the medical staff.[39] EHR is another tool for taking care of patients, and it should naturally develop among physicians who share patients. As a practical matter, physicians are more likely to adopt EHR if they can work with the larger systems they already rely upon for specialized care of patients. We also believe that group practices should be able to donate to physicians who are not members, employees or independent contractors, under the same criteria that should apply to hospitals.

By widening the range of permissible recipients to include physicians who are not on the medical staff of the donor hospital, CMS will more effectively promote true interoperability and improve the quality of care that comes from physicians and patients being connected to health information whenever and wherever needed than by any other

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

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

change in the proposed rules. This is because these physicians, by definition, have their primary hospital affiliation with another hospital, and consequently will want the donor's EHR system to be interoperable with the system that is developed at their primary hospital.

Given the purposes behind EHR adoption, the comment sponsors hope to use the CMS EHR exception to target donations, incrementally and over time, as technology develops and budgets allow, to maximize the benefit of the donations around legitimate objectives. Donations would consider a number of objectives, including connecting physicians with whom we share the most patients (thus maximizing the benefits of EHR to the largest number of patients); connecting physicians who treat specific diseases or have medical concerns[40] we have targeted for improvement through use of EHR; connecting physicians who work together to achieve quality outcomes or pay for performance objectives that would be advanced by use of a common EHR; and connecting our physicians and facilities with "safety net" providers who often serve the uninsured and do not have the resources to adopt an EHR without help. We believe we can achieve these objectives under the language in the proposed post-interoperability exception that allows donations if "neither the eligibility of a physician for the items or services, nor the amount or nature of the items and services, is determined in a manner that is directly related to the volume or value of referrals or other business generated between the parties," but only if "directly related to" is interpreted to allow donations to achieve the legitimate objectives identified above.

We support CMS "deeming" certain conduct to be permissible under the "directly related to" standard, and are especially supportive of the "deemed" standard allowing donations if the "determination is made in any reasonable and verifiable manner that is not directly related to the volume or value of referrals or other business generated between the parties." § 411.357(x)(4)(vi). However, we are concerned that the conduct "deemed" acceptable be broad enough to allow the proper identification of potential recipients, such as on the basis of the factors suggested above.

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

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

protocols, which are built into EHR systems. The fact that the treatment of heart disease, by its nature, involves substantial referrals of designated health services should not make that donation suspect. To the contrary, it should be welcomed as a way to improve care and reduce hospitalization of heart patients.

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

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

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

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

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

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

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

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

employer) or any network or IPA the physician may be using to acquire EHR. If the donation is given to the physician's group or employer, everyone in the group involved in care of shared patients should be allowed to use the donated technology and services.[41]

3. The donor should be allowed to decide not to give a donation if it determines a physician, physician group, physician employer, or physician network should be excluded on some legitimate criteria,[42] even if it means that individual physicians who otherwise meet the criteria for receiving a donation are excluded.

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

D. Value of Protected Donations

We urge CMS not to cap EHR donations. As potential donors, it is quite clear that the other requirements of this proposed rule and sheer economic reality will prevent excessively large donations that raise a realistic likelihood of program abuse, especially given the Stark incorporation of the anti-kickback statute, which would punish unusually large donations intended to induce referrals. The sponsoring organizations do not expect to make large donations to individual physicians or their practices.[43] Thus, while a cap may actually be in the economic best interests of potential donors, we oppose such a measure because it is expensive and difficult to track, especially under a strict liability

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

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

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

law where harmless mistakes (such as the failure to correctly identify the donation or to correctly calculate or document its value) create substantial penalties.

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

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

Donations of updates and upgrades should be excluded from any cap because they are difficult to prospectively value and occur often to bring the EHR into compliance with new laws and regulations or to introduce or improve evidence-based clinical protocols and alerts. We expect that interoperability will require constant updates and upgrades over time in EHR systems.[44] CMS should encourage constant improvement in EHR systems. Imposing a burdensome requirement of valuing and documenting such donations will reduce innovation and improvement. Furthermore, it is difficult to see program abuse resulting from this kind of donation.

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

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

Finally, to the extent CMS believes a cap is necessary, it should give donors the maximum flexibility to address any cap requirement. Donors should be able to limit donations to a certain amount per physician or to a percentage of the value of the donation subject to the cap, in their discretion. The cap should be a life-time cap, rather than constrained into a short number of years, and it should be an aggregate cap, rather than an annual cap. CMS should accept any reasonable, objective methodology to value services under the cap, including approximations.

E. Certification and Documentation Requirements

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

With regard to the documentation standards in § 411.357(x)(5)(i)(ii) and (iii), while we recognize that it is consistent with other Stark exceptions to require a writing signed by the parties, specifying covered items or services and the value of those items or services, and covering all such services, we do not believe the same stringent documentation standards should apply in the very complex context of EHR. In particular, we urge that CMS drop the requirement documenting the "value" of the donated items and services, especially the training and technical support, for the reasons suggested above in the discussion in Section II.A.3. of the cap and the value of the donated items and services.[45] If documentation of "value" is required at all, it should be in the context of the anti-kickback safe harbor where a technical failure to satisfy this requirement does not automatically trigger penalties.

We also request that CMS not require that the writing specify in detail donated software, training, and technical support because of the difficulty—amounting to near impossibility—of doing so when much of what will be needed will occur after the initial donation and documentation. If required at all, such a requirement should be in the context of the anti-kickback safe harbor, where a technical failure to satisfy the

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

requirement does not automatically trigger penalties. However, if CMS requires documentation specifying the items or services being donated, it should require only a general statement that the donor will provide training and technical support connected to EHR, in accordance with internal guidelines, and should not require valuation of training and technical support.[46] With regard to software donations, it should define updates and upgrades as covered by the initial donation, without requiring additional documentation, even if subsequent upgrades are discretionary and require payment of an additional fee.[47] Only donations of new software (not updates and upgrades of existing software) should need to be documented, and it should be acceptable for that to be done by an addendum or in any other reasonable manner, including e-mail communication between the donor and recipient.

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

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

A narrower pre-interoperability exception cannot be justified based upon a reasonable concern with program or patient abuse, especially given reasonable conditions that promote ongoing efforts toward interoperability. For two reasons, we believe CMS's concerns about pre-interoperability program abuse related to the creation of "stand-alone electronic health records systems"[48] is based upon an inaccurate understanding of current developments in EHR systems and markets, as explained below.

First, interoperability is a process. Even now, as EHR software systems are being built piece by piece and updated constantly, organizations are continually working to create interfaces and connections that allow electronic communications about patients.

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

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

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

The interfaces and connections are both within the EHR system—allowing, for instance, a hospital EHR system to access the lab system and the clinic records—and between the EHR system and administrative systems, such as billing and coding. Organizations also are actively working with vendors and other health care organizations on creating health information networks and on direct connections between different systems' EHR. Once physicians are accustomed to EHR and the benefits for their patients, they push to obtain electronic access to records as they or their patients move between facilities and different EHR systems. While CMS envisions the regulatory step from pre-to-post interoperability as a huge step, for EHR system vendors and owners that step will be simply the next step of an extended process they have been engaged in for quite some time.

Second, CMS suggests that some donors might see a market advantage to "stand-alone" EHR systems that would be anti-competitive.[49] We see none of this; indeed, we see that "stand-alone" systems are not favored in the market and will not last long in light of ongoing efforts to develop interoperability standards. Indeed, the path to interoperability and away from "stand alone" systems already exists in contracts. For years, purchasers of EHR systems have insisted upon and received contractual assurances that their systems will be updated or upgraded to meet federal standards as they are promulgated.[50] EHR systems (or, more likely, components of systems) that do not update or upgrade to meet interoperability standards will quickly become obsolete and will be replaced by others that meet those standards. Stand-alone systems will simply not continue to be supported post-interoperability based on any kind of perceived market advantage related to forcing referrals within the system. Physicians will not tolerate that kind of closed system once alternatives are available, because it is detrimental to patient care and is inconvenient. All of the sponsors of this comment, whether they have their own proprietary system or a vendor system, expect to meet interoperability standards in order to continue to have a system that is connected, rather than isolated.

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

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

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

would have serious difficulty making donations under the pre-interoperability rule, as proposed.

While CMS has stated that it expects interoperability standards to be adopted by the Secretary by the third quarter of 2006, we are concerned that this time frame may be optimistic. Furthermore, CMS has stated that it will not finalize post-interoperability rules until after the Secretary has adopted interoperability standards. 70 Fed. Reg. at 59190. That means that even if interoperability standards are promulgated by the third quarter of 2006, it is likely to be 2007 before donors know what they will be able to do under the post-interoperability EHR rule, and it could take much longer than that if the expected date for interoperability standards turns out to be optimistic. This makes budgeting for donations very difficult and delays EHR adoption by physicians unnecessarily and unwisely.

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

A. Eliminate Unnecessarily Restrictive Definitions and Uses of EHR

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

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

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

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

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

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

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

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

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

To further address CMS's concern about program abuse pre-interoperability, we would support an additional condition that would require donated EHR software to be subject to contract terms that require that it will be updated or upgraded to meet interoperability standards within some reasonable time after they are adopted. While donors could not guarantee that the vendors who make such promises will actually be able to succeed in making the donation interoperable, we expect that most vendors will

both accept such language (because many are doing it now) and will in fact comply (because otherwise they will go out of business due to inability to sell their product).

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

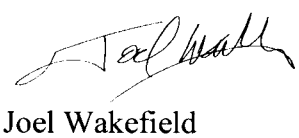
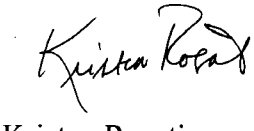
IV. Conclusion

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

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

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

Sincerely,


Joel Wakefield

Kristen Rosati

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Submitter : Mr. Richard Latuchie **Date:** 12/12/2005

Organization : Regional Health, Inc.

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1303-P-42-Attach-1.DOC

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., 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;

My name is Richard Latuchie. I am the Vice President, Business Development & Information Systems for Regional Health, an integrated Health Delivery System located in Western South Dakota. Regional Health is comprised of five hospitals, including our flagship, Rapid City Regional Hospital, a 350- bed tertiary care facility serving the Western half of South Dakota, as well as neighboring areas in Nebraska and Wyoming. It also includes nursing homes, assisted living facilities, and physician clinics. I appreciate the opportunity to comment on the proposed rule outlining an exception to the Physician Self-Referral regulations. These regulations, along with their counterpart anti-kickback regulations pose a significant barrier to us in trying to work with physicians in the communities we serve in building an information technology infrastructure to improve the coordination and quality of care.

We operate with a mixture of employed and independent physicians in our community. Many of the independent physicians are reluctant to invest the large sums necessary to develop electronic medical records systems in their clinics. This is particularly true for the many physicians who still practice as individual practitioners or within small groups.

The Stark law imposes severe penalties on hospitals and physicians that violate it, and as a hospital operating under a CIA, Rapid City Regional Hospital is particularly sensitive to any action that could be interpreted as violating this and related regulations and laws. We therefore, were happy to see the intent of the proposed regulations, because providing an exception to the Stark rules for e-prescribing and EHRs will accelerate physician use of health informatics.

There are a number of points I would like to address:

- In the absence of a certification process to be used, I do not thing that having two distinct EHR Exceptions is a good idea. It creates another level of uncertainty, which unfortunately is often a reason to not do anything.

- I am in favor of using a broader exception consistent with the mandate of section 1877 (b)(4). The benefits of increased use of Healthcare IT are clear, and I do not

see the downsides or potential for abuse that apparently contributed to a narrower view of the HER-related Stark exceptions.

- The systems I am familiar with are much broader than e-prescribing only. It does little good providing this narrow exception, as e-prescribing is deeply embedded in many of the clinical systems that we utilize. The incentives ought to be directed toward greater integration, rather than stand-alone systems.

- In its pre-interoperability HER exception, the lack of clear guidance as to what "necessary" services are will create a high level of uncertainty. Unless physicians can make the required equivalency determination without engaging consultation services, physicians will simply not be willing to proceed. And the risk for us, in terms of the lack of clarity, would be a barrier as well.

- According to the proposed regulations, EHR software should not include administrative functions, and any training we provide to physicians must be directly related to the software. First, it is extremely unlikely that appropriate software will not have administrative functions. And it is entirely possible that we will need to help the physicians maintain the infrastructure necessary to connect to us, going beyond the strict definitions you define.

- I don't think that it is wise to require that permitted support conform to the BioSense standards. These standards have not been widely discussed or adopted industry-wide.

- Your definition of permissible donors is problematic, in that we now employ six hospitalists, and therefore some of the physicians who would be most in need of data interoperability may in the future not have admitting privileges. I would urge CMS to change the criteria to physicians on the medical staff whose patients frequently receive inpatient or outpatient care at the hospital.

- I would urge you to drop the provision that prohibits us from using IT to entice physicians away from other hospitals. Physicians may make the judgment that it is in their patients' best interest to work with the hospital that provides the best clinical care, and I fear that this would be interpreted after the fact as trying to entice physicians away from other facilities.

- I am also against any attempt to cap the value of the services which we might offer to physicians. We will be limited by our budgets, and would welcome the subsidy of these costs by the Federal government. In the absence of those subsidies, we have to be guided in our decisions by what makes sense, from financial and clinical standpoints. The current imposition of a cap on the value of donated technology will inhibit the wide-spread adoption that I believe you wish promote.

Thank you for the opportunity to comment on your proposed regulations. I strongly believe they are a step in the right direction, that could, if implemented appropriately, lead to higher quality care, and fewer medical errors.

Sincerely,

Richard S. Latuchie
Vice President, Business Development & Information Systems
Regional Health
Rapid City, SD

Submitter : Mr. Thomas Leary **Date:** 12/12/2005

Organization : Healthcare Information and Management Systems Soc.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1303-P-43-Attach-1.DOC

CMS-1303-P-43-Attach-2.DOC

HIMSS

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December 14, 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:

The Healthcare Information and Management Systems Society (HIMSS) is pleased to submit our comments regarding the Centers for Medicare and Medicaid (CMS) Proposed Rule, entitled, " Medicare Program; Physicians Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing Arrangements," (42 CFR Part 411), on providing Stark Regulation Exception for electronic prescription services (E-Prescribing) and Electronic Health Records (EHRs). We applaud you and your colleagues at the Department of Health and Human Services Office of the Inspector General for recognizing that regulatory changes are necessary to ensure the healthcare community can incorporate advances in health information technology (HIT) into healthcare quality and patient safety initiatives. The proposed Stark Regulation Exception, along with the proposed Safe Harbors for E-Prescribing and EHRs, are important steps toward overcoming a leading barrier to Health Information Technology adoption in healthcare delivery, particularly in the ambulatory care setting. Reducing the burden of these barriers will permit healthcare professionals, facilities, and industry address the adoption gap and lay the groundwork for interoperable healthcare data sharing envisioned for a National Health Information Network.

HIMSS is the healthcare industry's only membership organization exclusively focused on providing leadership for the optimal use of healthcare information technology and management systems for the betterment of healthcare. HIMSS represents nearly 18,000 individual, 275 corporate members, and 43 chapters nationwide. HIMSS is committed to achieving the benefits of EHRs and has had considerable discussion within our membership on the barriers to widespread adoption of HIT solutions. By bringing industry experts together through our volunteer structure, HIMSS hopes to offer a coordinated voice to the national discussion on these important healthcare issues.

HIMSS offers its support and appreciation to the Department for leadership in addressing the Stark regulation exception for E-Prescribing and Electronic Health Records. As you stated at the HIMSS Public Policy Forum in October 2004:

> *"We need to supplement [nation-wide standards for E-Prescribing and pay for performance] activities with some direct incentives and direct support for E-Prescribing adoption in doctors' offices right now. The Medicare [Modernization Act] gives us a new authority to develop an exception to the so-called Stark law, Stark regulation and in anti-kickback safe harbor to allow hospitals and medical practices and plans participating in Medicare drug benefits to provide physicians with non-monetary support that can make e-prescribing easier."*

Our response recommends the proposed rules provide the following:

- Replace the notional capitation ceilings with a graduated process that allows for higher volume donations early in the process and has set start dates for providers to enter into contractual agreements that moves the relationship from a donor-recipient to a financial exchange

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- Consider broadening the list of donors and recipients to allow for a greater number of scenarios for encouraging HIT adoption
- Align interoperability and standards setting efforts with ongoing federal and private sector initiatives, including the Standards Harmonization and Certification Commission for Health IT contracts, and the Integrating the Healthcare Enterprise Initiative
- Enable clinicians to use a common tool for tasks to streamline workflow, encourage IT usage, and thus improve patient safety and healthcare quality
- Incorporate process with the national efforts to streamline biosurveillance and response and disaster management initiatives
- Grant EHRs and E-Prescribing technologies equal exceptions and safe harbors to maintain a level competitive environment in the marketplace

We look forward to working with CMS, the OIG, and our healthcare industry colleagues to make responsible changes to the Stark and Anti-Kickback Act regulations that will maximize HIT implementation in support of improved patient safety and healthcare quality. If you have any additional questions please contact Mr. Thomas M. Leary, Director, Federal Affairs, tleary@himss.org, or 703.837.9814.

Sincerely,

H. Stephen Lieber, CAE President and CEO HIMSS	Blackford Middleton, MD, MPH, MSc, FHIMSS Chair, HIMSS Board of Directors
	Center for Information Technology Leadership
	Clinical Informatics Research & Development Partners Healthcare System Harvard Medical School

HIMSS Response to HHS Proposed Rules Providing Stark Exceptions and Anti Kick Back Act Safe Harbors for Certain Electronic Prescribing Arrangements

***December* 2005**

Issues and Questions

The Healthcare Information and Management Systems Society (HIMSS) is pleased to submit our comments regarding the Office of the Inspector General (OIG) Proposed Rule, entitled, " Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute (42 CFR Part 1001 RIN 0991-AB39) and the Centers for Medicare and Medicaid (CMS) Proposed Rule, entitled, " Medicare Program; Physicians Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing Arrangements," (42 CFR Part 411), on providing Anti-Kickback Act and Stark Regulation Exception for electronic prescription services (E-Prescribing) and Electronic Health Records (EHRs). The proposed rules are important steps toward overcoming a leading barrier to Health Information Technology (HIT) adoption in healthcare, particularly in the ambulatory care setting. Reducing the burden of these barriers will permit healthcare professionals, facilities, and industry address the adoption gap and lay the groundwork for interoperable healthcare data sharing envisioned for a National Health Information Network.

HIMSS is the healthcare industry's only membership organization exclusively focused on providing leadership for the optimal use of healthcare information technology and management systems for the betterment of healthcare. HIMSS represents nearly 18,000 individual, 275 corporate members, and 43 chapters nationwide. HIMSS is committed to achieving the benefits of EHRs and has had considerable discussion within our membership on the barriers to widespread adoption of HIT solutions. By bringing industry experts together through our volunteer structure, HIMSS hopes to offer a coordinated voice to the national discussion on these important healthcare issues.

The following response is reflective of the diverse membership base, and attempts to provide an understanding of the impact of the proposed rules on these broad constituencies within the healthcare community. Our approach to the response was to identify common questions and themes presented by the Office of the Inspector General and the Centers for Medicare and Medicaid Services. The response cites the questions embedded in each of the proposed rule, which should aid in the review and cross-referencing of the document.

Additionally, HIMSS suggests the OIG and CMS encourage a broad scope to the proposed rules that take into account the unique differences between the needs of ambulatory practices and hospitals. As it is well-documented, the workflow and information needs of office-based clinicians are fundamentally different than those of hospital-based clinicians. HIMSS 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 an open, transparent RFP process typically used in government sponsored tenders. 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 provides a safeguard against lock-in by the donating entity. We look forward to the opportunity to discuss these perspectives at a time in the near future.

The HIMSS response is as follows:

1. CMS/OIG request for comment on the definition of "necessary" and "used solely" no monetary remuneration.

CMS: (Federal Register page 59185): We do not interpret the term ``necessary'' to preclude upgrades of equipment or software that significantly enhance the functionality of the item or service. We believe that restricting the exception to ``necessary'' items and services is important to minimize the potential for abuse. However, we recognize that the donors of the items and services will not necessarily know which items and services the physician already possesses or has obtained.

HIMSS appreciates the opportunity to comment on the issue of necessary no monetary remuneration. HIMSS recommends that electronic health records should be given similar treatment to E-Prescribing. We are concerned that the distinctions drawn between software and hardware effectively do not include hardware from the EHR safe harbor, but includes it in the eRx Safe Harbor. We understand the legal challenges outlined by the provisions in the Medicare Modernization Act; however, the distinction does not seem practical, especially in a context where the EHR must include eRx to qualify for safe harbor.

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 E-Prescribing, as opposed to other services. Practices need guidance on connectivity as much as on hardware or software. HIMSS suggests that connectivity should be a defined benefit of the agreement on the safe harbor, as opposed to a defined contribution and recipients encouraged to select the 'wireless, broadband' access that best meets the provider's business needs.

Donations relative to connectivity should be limited to any necessary devices for connectivity and support for selecting and installing appropriate connectivity services, but not include connectivity fees. Fees for connectivity should be an ongoing expense recognized by the prescribing provider and, if included in the donation, may not be sustainable beyond any cap which may result in discontinued use of the donation.

2. OIG/CMS request comment on the issue of certification process for no monetary remuneration and whether a recipient should be required to submit a written statement on owned or donated services.

OIG: (Federal Register page 59018): "Therefore we are proposing at §1001..952 (x) (7-8) that the Donor must not have actual knowledge of, and not act in reckless disregard or deliberate ignorance of, the fact that the Recipient possess or has obtained items and services that are technically or functionally equivalent to those donated by the Donor. The Recipient would be protected only if the certification is truthful. We are soliciting comments about other ways to address this concern."

CMS: (Federal Register page 59185): "Accordingly, Sec. 411.357 (v) (7) (iv) would require the physician to certify that the items and services provided are not technically or functionally equivalent to those that the physician already possesses or has already obtained. The physician must update the certification prior to the furnishing of any necessary upgrades or items and services not reflected in the original certification. The certification must be truthful, and we are proposing at Sec. 411.357(v)(8) that the DHS entity must not have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the physician possessed or had obtained items and services that were technically or functionally equivalent to those donated by the entity."

HIMSS is concerned that the process of provider self-certification as to the lack of technical or functional equivalence contemplated in the proposed rules will be unduly burdensome on the provider and may well have a "chilling" effect on the deployment of both E-Prescribing (eRx) and Electronic Health Record (EHR).

HIMSS suggest 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, physician assistants, and Midwives in the Stark Regulation Exception for electronic prescription services (E-Prescribing) and Electronic Health Records (EHRs).

3. OIG/CMS ask respondents to comment on the OIG's proposed safe harbor for the donation of limited hardware, OS software, and connectivity services.

OIG: (Federal Register page 59019): "Accordingly, we are proposing using our regulatory authority under section 1128B (b) (3) (E) of the Act to create an additional safe harbor to promote the provision by Donors to Recipients of some limited hardware (including necessary operating system software) and connectivity services that are used for more than one function so long as a substantial use of the item or service is to receive or transmit electronic prescription information. We propose to treat operating software as integral to the hardware and distinct from other software applications that are not necessary for the hardware to operate."

CMS (Federal Register page 59185): "Accordingly, we are proposing to use our authority under section 1877(b) (4) of the Act to create an additional exception to protect the provision by DHS entities to physicians of hardware (including necessary operating system software) and connectivity services that are used for more than one function, so long as a substantial use of the item or service is to receive or transmit electronic prescription information. We propose to treat operating software as integral to the hardware and distinct from other software applications that are not necessary for the hardware to operate. Under this additional exception, protection would not extend to the provision of items or services that are only occasionally used for electronic prescribing. The additional exception would incorporate the definitions and conditions set forth in this proposed rulemaking and would also include conditions to address the additional risk of abuse posed by multi-functional items and services."

The proposal raises an excellent question on donation of hardware, Operating System (OS) software, connectivity services, etc. Like HHS, HIMSS 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, we recommend that the safe harbor be extended to cover these elements.

HIMSS suggests the Department consider offering guidance on the term 'substantial'.

4. OIG/CMS ask respondents to comment on the standards that should appear in an additional safe harbor for multi-functional hardware, to include methodologies for quantifying or ensuring that substantial use of hardware and connectivity services is for E-Prescribing.

OIG: (Federal Register page 59019): "We are soliciting public comment about the standards that should appear in an additional safe harbor for multi-functional hardware (including necessary operating system software) or connectivity services."

CMS (Federal Register page 59185): "We are soliciting public comment about the standards that should appear in an additional exception for multi-functional hardware (including necessary operating system software) or connectivity services. In particular, we are soliciting public comment on methodologies for quantifying or ensuring that a substantial use of hardware and connectivity services is for the receipt or transmission of electronic prescribing information."

HIMSS fully expects the Department to incorporate the standards outlined in the E-Prescribing final rule that was released in November 2005, as well as the 20 standards identified in the Consolidated Health Informatics initiative into the final regulation, with particular emphasis on the National Council on Prescription Drug Programs (NCPDP) standards for ordering drugs from retail pharmacies to standardize information between health care providers and the pharmacies. As you know, NCPDP V3.2 was created by the NCPDP Telecommunication Work Group (Work Group One). The objective of the standard is to provide a standard format for on-line real time adjudication for pharmacy claims. Functions include billing of pharmaceutical products including compound medications; billing of professional drug utilization review situations. Users of the standard include administrative/reimbursement and clinical environment. Pharmacies submit claims for drugs and professional services and when applicable receive clinical DUR information derived from payer/prescription benefit manager databases. The standard is used in all operating system environments and claims are submitted and then adjudicated directly from pharmacy to payer and via network. The standard satisfies the needs of public and private prescription benefit plans for well over 100,000,000 health plan members. In addition, this standard facilitates a specific type of business communication between a large number of diverse parties within the third party environment. To do this successfully, it must accomplish the following tasks:

- Support the needs of as wide a base of potential users as possible.
- Maximize use of existing relevant standards wherever possible (e.g. Version 1.0 of this standard).
- Be flexible enough to change as needs and technology change.
- Be unambiguous.
- Be easy to implement by payers and pharmacy management software developers.

Additionally, as an original co-sponsor of the Integrating the Healthcare Enterprise (IHE) Initiative in the United States, along with the American College of Cardiology (ACC) and the Radiological Society of North America (RSNA), HIMSS strongly suggests including the IHE process as a proven tool for standardizing accepted standards. IHE is a multi-year, global initiative that creates the framework for passing vital health information seamlessly—from application to application, system to system, and setting to setting--across multiple healthcare enterprises. IHE brings together healthcare information technology stakeholders to implement standards for communicating patient information efficiently throughout and among healthcare enterprises by developing a framework for interoperability.

In its seven-year history, IHE has succeeded in engaging vendors and establishing implementation momentum. IHE has developed a unique process for producing its framework for interoperability by: (1) combining the collaboration of the primary stakeholders in an efficient and focused manner; (2) operating on a yearly cycle to ensure rapid and immediately applicable steps; (3) providing practical tools and information resources that facilitate adoption of standards-based integration solutions, and (4) enabling both healthcare entities and vendors to improve access to information incrementally.

Finally, we were pleased to hear at the American Health Information Community (AHIC) meeting on November 29, 2005, that the Department is considering asking the Certification Commission on Health

IT to develop a certification process for E-Prescribing. If the Department does move in this direction, we encourage the Department to clarify with CCHIT, whether there will be a certification category for stand alone E-Prescribing tools, or if it will be incorporated in one of the three existing process categories.

Ultimately standards and a certification process will be critical to the success of the adoption of E-Prescribing tools. Without final standards publication, the industry will wait on the adoption of any technology or technical approach, rather than investing in any technology that does not enable compliance with identified and accepted standards.

5. OIG/CMS ask respondents to comment on the nature and amount of a cap on donated multi-functional hardware and connectivity services.

OIG: (Federal Register page 59019): "We are also soliciting public comment on the nature and amount of any cap that might impose on the value of the donated multi-functional hardware or connectivity services."

CMS: (Federal Register page 59185): "We are soliciting public comment about the standards that should appear in an additional exception for multi-functional hardware (including necessary operating system software) or connectivity services. In particular, we are soliciting public comment on methodologies for quantifying or ensuring that a substantial use of hardware and connectivity services is for the receipt or transmission of electronic prescribing information.

HIMSS appreciates the complexity of this item given the many concerns regarding the method of defining an economic cap. HIMSS recommends the proposed regulation contain no capitation; however, if caps are used, the Department needs to take into consideration the following negative impact on the market and providers, in particular,

1. A cap could set the price indirectly;
2. Any cap would need to cover not just the hardware, but the connection, software, support and other related service for eRx and EHR;
3. eRx and EHR are two significantly different price points;
4. The manager of the service needs to be defined (hospital, other provider, etc.)

Ultimately, the challenge is that many products on the market are integrated, so a cap becomes very difficult to set. Perhaps the Department should consider identifying a scaled incentive period where donation levels would be at their greatest level early in the implementation process, and would steadily decrease over the course of 12-24 months. If providers know the donation parameters going into the process, they can make financial and budgetary decisions accordingly.

HIMSS has additional concerns for the Department to consider.

First, the Department should consider clearly defining the scope and length of coverage for training and support services. Left to the market, the level of training and support services could become a selling point that has unintentional impact on the intent of the safe harbor.

Second, by limiting donations to E-Prescribing systems only would adversely impact vendor products that offer integrated EHR systems, which would not be covered under the safe harbor as currently written. HIMSS strongly encourages the Department to review this section of the proposed regulations to consider a modification that would allow vendors with integrated EHR systems to compete in the marketplace with the same level of safe harbor.

Third, HIMSS encourages the Department to consider measures to protect providers and smaller facilities from being locked out of the market by more robust information systems offices at larger hospitals that will be able to use economies of scale to offer more robust services and response times that smaller facilities can not compete against.

6. OIG/CMS ask respondents to comment on whether a safe harbor should be extended to items and services provided to other individuals or entities of a hospital (in addition to hospital physicians).

OIG: (Federal Register page 59019): "We do not intend to interpret this provision as extending to physicians who do not routinely furnish services at the hospital. We do not intend for this exception to protect remuneration that is used to induce physicians who already use other hospitals to join the medical staff of a different hospital. We are soliciting public comment on whether we should include items or services provided to other individuals or entities (e.g., other health care prescribing professionals who treat patients at the hospital."

CMS: (Federal Register page 59186): "We are soliciting comments regarding whether and how a group practice may appropriately furnish qualifying electronic prescribing technology to a ``physician in the group practice," as defined at Sec. 411.351."

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

HIMSS 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' to show clearly and deliberately the fairness of the proposed regulation and the intent to include Nurse Practitioners and Midwives in the Stark Regulation Exception for electronic prescription services (E-Prescribing) and Electronic Health Records (EHRs). .

An additional consideration should be made for research and manufacturing entities (pharmaceutical manufacturers, biotechnology companies, etc.) to serve as potential donors of software and hardware services with appropriate provisions to safeguard against preferential product placement. Blind trusts or foundations utilizing funds from several pharmaceutical companies might be used to obviate this moral hazard.

7. OIG/CMS 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.

OIG: (Federal Register page 59019-20): "Finally, we are soliciting comments on whether there is a need to protect other categories of Donors or Recipients beyond those specifically set forth in section 1860(D) -4(e)(6) of the Act and if so, how best to address safe harbor protection for those individuals or entities. In particular, we are interested in comments addressing the types of individual and entities that should be protected, the degrees of need for protection, and the safeguards that should be imposed to protect against fraud and abuse."

CMS: (Federal Register page 59186): "We are soliciting comments on whether we should use our authority under section 1877(b) (4) of the Act to protect qualifying electronic prescribing technology provided to physicians by other DHS entities. Most other DHS services do not appear to involve substantial utilization of prescription drugs. We are interested in comments addressing the types of DHS entities that should be included, the degree of need for the protection, and the safeguards that should be imposed to protect against program or patient abuse."

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

As for the list of donors, HIMSS encourages the Department to consider including Integrated Delivery Networks, as well as, RHIOs and Healthcare Integration Enterprises (HIE) that are neutral parties that are note seeing individual referrals from providers.

The development and deployment of RHIOs is a public policy priority articulated by both the President and Congress. Including RHIOs as appropriate donors for purposes of safe harbor could incent physician participation in community RHIOs. Therefore, the definition of a RHIO should be broadened to include any consortium of entities working collaboratively to support the initiative to create/maintain a Community-based Health Record/EHR, which provides benefit to the community at large. The expansion of this definition would enable the RHIO organization to potentially provide subsidies and /or discounts to local physicians, thus reducing the barrier to participation in the EHR.

An additional consideration should be made for research and manufacturing entities (pharmaceutical manufacturers, biotechnology companies, etc.) to serve as potential donors of software and hardware services with appropriate provisions to safeguard against preferential product placement. Blind trusts or foundations utilizing funds from several pharmaceutical companies might be used to obviate this moral hazard.

8. OIG/CMS ask respondents to comment on whether the safe harbor should extend to non-drug prescriptions.

OIG: (Federal Register page 59020): "We are soliciting comments on whether the safe harbor should protect qualifying electronic prescription technology that is used for the transmission of prescription information regarding items and services that are not drugs (e.g., supplies or laboratory tests.)"

CMS: (Federal Register page 59186): "We are soliciting comments on whether the exception should permit qualifying electronic prescribing technology to be used for the transmission of prescription information regarding items and services that are not drugs (for example, supplies or laboratory tests)."

In order to encourage provider utilization of E-Prescribing technology to increase safety, cost-effective practice, and efficiency, the Office of the Inspector General should support the use of E-Prescribing technology for all the functions currently accomplished through writing prescriptions. This includes prescribing medical supplies (insulin syringes) and durable medical equipment (wheelchairs). If sponsored E-Prescribing systems could not be used for non-drug prescriptions and should not extend to 'laboratory prescriptions' e.g. blood monitoring associated with the management of diabetes that would disrupt workflow and create a disincentive for the use of E-Prescribing technology.

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9. OIG/CMS request respondents to comment on their proposed definition of Interoperable

OIG: (Federal Register page 59020): "We are soliciting public comment about this approach, our definition of the term "interoperable," alternative means of ensuring the maximum level of interoperability, and the types of software currently available for electronic prescribing."

CMS: (Federal Register page 59186): "We are soliciting public comment about this approach, our definition of the term ``interoperable,'' alternative means of ensuring the maximum level of interoperability, and the types of software currently available for electronic prescribing."

In light of the Department's industry supported effort to harmonize terms and standards, HIMSS encourages the Department to incorporate the definition of interoperable that has been promulgated by the Certification Commission for Health IT. The CCHIT definition, which will be integral to the certification of the EHR systems that the Department is referencing, has completed a public comment period and is being increasingly accepted as the industry standard. The interoperability requirements read as follows: (insert definition)

2. Interoperability Requirements
   - The patient information provided to donated EHR's must provide the same level of information interoperability (as defined by CITL levels of interoperability, Walker, Pan, et al, Health Affairs, January 19, 2005, pg. W5-11) as EHR's used by the donating entities physicians.
   - The enabler for portability is in ensuring interoperability amongst all IT systems in range of care that the patient encounters, where interoperability is defined as the uniform and efficient movement of electronic healthcare data from one system to another such that the clinical or operational purpose and meaning of the data is preserved and unaltered.
   - Interoperability requirements has 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 policy component provides the "rules of the road" as to what minimum types of data should be exchanged, the equity of availability of the information to all entities that require exchange capability within the affected healthcare market.
   - We believe that the policy component must be used to drive the market to demand the technology component of interoperability of electronic healthcare records. With the exception of the 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.
   - Interoperability in healthcare is complex. Government mandated interoperability standards will always lag product and market innovations. That is why we believe that interoperability requirements must be driven by predicating the receipt of government financial and regulatory incentives on conditions that demand interoperability in practice.
   - 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 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.
   - The definition of an EHR must not explicitly or implicitly be only the EMR/clinical component or combined EMR/Practice management components. It must be any component of information management software used by a physician or medical group to operate the medical practice (i.e. Practice management applications that have additional decision support capabilities that allow for a more robust EHR (eligibility and claims data)). Data from billing and scheduling system 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.

10. OIG/CMS 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.

OIG: (Federal Register page 59020): "We are considering whether to limit the aggregate fair market value of all items and services provided to a Recipient from a single Donor... We are soliciting public comment on the amount of a cap that would adequately protect the program against abuse, the methodology used to determine the cap (for example fixed dollar amount, percentage of the value of the donated technology, or another methodology), whether the same cap would be adequate if there were protection for the donation of multi-functional hardware and connectivity services, whether the cap should be reduced over time, an whether the cap places a disadvantage on smaller entities that do not have the financial resources of larger chains or organizations."

CMS: (Federal Register page 59186): "We are soliciting public comment on the amount of a cap that would adequately protect the program against abuse, the methodology used to determine the cap (for example, fixed dollar amount, percentage of the value of the donated technology, or another methodology), whether the same cap would be adequate if there were protection for the donation of multi-functional hardware and connectivity services, whether the cap should be reduced over time, and whether the cap places a disadvantage on smaller entities that do not have the financial resources of larger chains or organizations."

HIMSS appreciates the complexity of this item given the many concerns regarding the method of defining an economic cap. HIMSS recommends the proposed regulation contain no capitation; however, if caps are used, the Department needs to take into consideration the following negative impact on the market and providers, in particular,

1. A cap could set the price indirectly;
2. Any cap would need to cover not just the hardware, but the connection, software, support and other related service for eRx and EHR;
3. eRx and EHR are two significantly different price points;
4. The manager of the service needs to be defined (hospital, other provider, etc.)

Ultimately, the challenge is that many products on the market are integrated, so a cap becomes very difficult to set. Perhaps the Department should consider identifying a scaled incentive period where donation levels would be at their greatest level early in the implementation process, and would steadily decrease over the course of 12-24 months. If providers know the donation parameters going into the process, they can make financial and budgetary decisions accordingly.

HIMSS has additional concerns for the Department to consider.

First, the Department should consider clearly defining the scope and length of coverage for training and support services. Left to the market, the level of training and support services could become a selling point that has unintentional impact on the intent of the safe harbor.

Second, by limiting donations to E-Prescribing systems only would adversely impact vendor products that offer integrated EHR systems, which would not be covered under the safe harbor as currently written. HIMSS strongly encourages the Department to review this section of the proposed regulations to consider

a modification that would allow vendors with integrated EHR systems to compete in the marketplace with the same level of safe harbor.

Third, HIMSS encourages the Department to consider measures to protect providers and smaller facilities from being locked out of the market by more robust information systems offices at larger hospitals that will be able to use economies of scale to offer more robust services and response times that smaller facilities can not compete against.

11. OIG/CMS ask respondents to comment on criteria for selecting medical staff recipients of donated EHR.

CMS: (Federal Register page 59187): "We are interested in comments with respect to other potential criteria for selecting staff recipients of donated technology."

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

12. OIG/CMS ask respondents to comment on whether the safe harbor for E-Prescribing components should extend to software that covers non-drug prescriptions and whether CPOE should be a covered requirement.

OIG: (Federal Register page 59022): "Additionally, we are soliciting comments with respect to whether we should require that electronic health records software include a computerized provider order entry "CPOE" component."

CMS: (Federal Register page 59187): "We are interested in comments with respect to other potential criteria for selecting staff recipients of donated technology."

HIMSS believes 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 E-Prescribing and EHR systems 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, there needs to be further clarification and understanding specific to the standards/certification of E-Prescribing as well as EHRs. The current lack of accepted standards could become a barrier to adoption, delaying implementation of existing systems pending finalization of said standards.

In order to facilitate safe E-Prescribing (for patients being discharged from the inpatient setting) using hospital information systems, the exemption should also cover the financial costs of interfaces and translation software between hospital medication ordering systems based on HL7 and outpatient E-Prescribing based on NCPDP SCRIPT used in outpatient E-prescribing and EMR software in physician offices. The exemption should also cover reconciliation of medication lists between outpatient E-prescribing and EMR software used in physician offices and hospital inpatient electronic medical records systems as this is a critical area for increased patient safety (targeted in JCAHO.2006 safety goals).

13 OIG/CMS ask respondents to comment on whether the safe harbor 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.

OIG: (Federal Register page 59022): "As with electronic prescribing technology, we are concerned that there may be a risk that Recipients would intentionally divest themselves of functionally or technically equivalent technology that they already possess to shift costs to Donors, and we are soliciting public comments on whether and how to address this situation."

CMS: (Federal Register page 59185): "We are also concerned that there may be a risk that physicians would intentionally divest themselves of functionally or technically equivalent technology that they already possess in order to shift costs to the DHS entity. We are soliciting public comments on how best to address this issue.

HIMSS appreciates the Department's interest in protecting the integrity of the Anti Kickback Act and Stark Regulations. However, given the common understanding that clinician adoption of HIT solutions is low because of the implementation process, it seems counterintuitive to think that clinicians will purposely give up their current E-Prescribing or EHR solution to force the costs to the donor. The time spent selecting, installing, and training for a new system is too great for a clinician to change to a new system strictly for the potential profit.

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

HIMSS believes that the Department should also consider a process for factoring depreciation or amortization of provider's existing technology assets that may be certified under the Certification Commission for Health IT, but may not be up to current technology standards. In an environment where adoption rates are less than optimum, early adopters of E-Prescribing and EHR technologies that have made a positive impact on patient safety and healthcare quality should not be penalized or excluded from the exception and safe harbor.

14. OIG/CMS ask respondents to comment on relevance to ensuring EHRs are compliant with Public Health Information Network and BioSense preparedness standards.

OIG: (Federal Register page 59022): "We are also considering requiring that protected software comply with relevant Public Health Information Network preparedness standards, such as those related to BioSense."

HIMSS is actively supportive of the work being accomplished by the federal government to develop the Public Health Information Network (PHIN). Through the work of our National Preparedness and Response (NPR) Task Force, we have authored several documents to help raise awareness of HIT issues. In the ideal state, the PHIN could provide greatly enhanced information gleaned from widespread adoption of EHRs, However, the process is slowed by the lack of an interoperability standard, HIMSS recommends that the Department develop a process that takes into account both current and future standardized solutions.

Additionally, HIMSS believes that clinicians and patients may be alarmed by the idea of clinician systems being linked to government systems for Biosurveillance purposes. HIMSS recommends using public service announcements and other effective tools to educate providers and the community on the HIPAA protections associated with electronic transmission of data, as well as the merits of providers using EHRs, particularly, faster public health reporting and surveillance as a byproduct of system of usage. Providers will be saved the challenges of manual reporting, and there is documented evidence that electronic surveillance can detect outbreaks sooner and will enable better communication and management processes.

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

15. OIG/CMS ask respondents to comment on whether EHRs should be granted the same program and beneficiary protections that exist for E-Prescribing.

OIG: (Federal Register page 59022): "In addition, electronic health records lack the program and beneficiary protections that exist under Part D prescription drug program and related electronic prescribing standards. We are considering including in the final safe harbor conditions designed to replicate these protections for electronic health records, including quality assurance measures. We are soliciting public comments on the most appropriate way to do so."

HIMSS appreciates the opportunity to comment on the issue of necessary no monetary remuneration. HIMSS recommends that electronic health records should be given similar treatment to E-Prescribing. We are concerned that the distinctions drawn between software and hardware effectively do not include hardware from the EHR safe harbor, but includes it in the eRx Safe Harbor. We understand the legal challenges outlined by the provisions in the Medicare Modernization Act; however, the distinction does not seem practical, especially in a context where the EHR must include eRx to qualify for safe harbor.

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 E-Prescribing, as opposed to other services. Practices need guidance on connectivity as much as on hardware or software. HIMSS suggests that connectivity should be a defined benefit of the agreement on the safe harbor, as opposed to a defined contribution and recipients encouraged to select the 'wireless, broadband' access that best meets the provider's business needs.

16. OIG/CMS ask respondents to comment on best process for determining the value of donated technology.

OIG: (Federal Register page 59022): "We are concerned that Donors may abuse the proposed exceptions for electronic prescribing items and services and electronic health records soft ware and training services by selectively relying on both exceptions to maximize the value of technology provided to Recipients as a means of misusing payments for referrals. We believe conditions should be included in the final regulation to prevent this abuse and are considering requiring an overall cap on value, as well as documentation requirements that integrate all technology provided under the final exceptions. We are considering requiring an overall cap on the value of donated technology (such that the value of technology donated under the electronic prescribing safe harbor would count towards the total value of the software protected under the pre-interoperability safe harbor)..."

HIMSS suggests that similar circumstances exist for both questions #16 and #18, and would encourage the Department to consider including Long Term Care Facilities, Integrated Delivery Networks, as well as, Regional Health Information Organizations (RHIOs) and Healthcare Integration Enterprises (HIE) that are neutral parties that are note seeing individual referrals from providers

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

19. OIG/CMS ask respondents to comment on whether the safe harbor should protect additional software applications, provided E-Prescribing, and EHRs are the core functions of the protected software, and whether CPOE should be included as a requirement.

OIG: (Federal Register page 59023): "We are soliciting public comments with respect to whether we should also or instead require that electronic records software include a CPOE component. We are also soliciting public comments on what types of software should be protected under the safe harbor and methods for ensuring that electronic prescribing and electronic health records are the core functions of the donated technology."

CMS: (Federal Register page 59190): "Additionally, we are soliciting comments with respect to whether we should also or instead require that electronic health records software include a computerized provider order entry (CPOE) component."

HIMSS believes 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 E-Prescribing and EHR systems 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.

HIMSS suggests that the scope of solutions within the safe harbors should be expanded to include at least registration and scheduling as this functionality also promotes the same public benefits as E-Prescribing (eRx) and Electronic Health Records (EHR) (greater system efficiency and reduced variance in health care delivery and results).

In addition, there needs to be further clarification and understanding specific to the standards/certification of E-Prescribing as well as EHRs. The current lack of accepted standards could become a barrier to adoption, delaying implementation of existing systems pending finalization of said standards.

20. OIG/CMS ask respondents to comment on whether the safe harbor should include other categories of donors and recipients

OIG: (Federal Register page 59023): We are considering whether to protect categories of Donors or Recipients, beyond those specifically set forth in section 1860D–4(e)(6) of the Act and whether different or alternative conditions should apply to any category of permissible Donors or Recipients. We are interested in comments addressing the types of individuals or entities that should be protected, the degree of need for protection, and the safeguards that should be imposed to protect against fraud and abuse.

CMS: (Federal Register page 59190): "We are proposing to protect the same categories of donors protected under the pre-interoperability exception as discussed in section II.B.1 of this proposed rule. We are also considering whether to protect additional categories of donors and whether different or alternative conditions should apply to any category of permissible donor. We are interested in comments addressing the types of individuals and entities that should be protected, the degree of need for protection, and the safeguards that should be imposed to protect against fraud and abuse."

HIMSS views the donor and recipient categories for EHR to be similar in scope to those for E-Prescribing and suggests the Department consider the comments outlined in our response under question # 7, which stated the following:

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

As for the list of donors, HIMSS encourages the Department to consider including Integrated Delivery Networks, as well as, RHIOs and Healthcare Integration Enterprises (HIE) that are neutral parties that are note seeing individual referrals from providers.

The development and deployment of RHIOs is a public policy priority articulated by both the President and Congress. Including RHIOs as appropriate donors for purposes of safe harbor could incent physician participation in community RHIOs. Therefore, the definition of a RHIO should be broadened to include any consortium of entities working collaboratively to support the initiative to create/maintain a Community-based Health Record/EHR, which provides benefit to the community at large. The expansion of this definition would enable the RHIO organization to potentially provide subsidies and /or discounts to local physicians, thus reducing the barrier to participation in the EHR.

An additional consideration should be made for research and manufacturing entities (pharmaceutical manufacturers, biotechnology companies, etc.) to serve as potential donors of software and hardware services with appropriate provisions to safeguard against preferential product placement. Blind trusts or foundations utilizing funds from several pharmaceutical companies might be used to obviate this moral hazard.

21. OIG/CMS ask respondents to comment on whether the safe harbor should identify a donation cap.

OIG: (Federal Register page 59024): "We are considering a cap on the value of the donated interoperable software that may be larger than the cap under the pre-interoperability safe harbor. With respect to a limiting cap, we are considering issues similar to those discussed in the preceding sections on the proposed electronic prescribing safe harbor and the proposed pre-interoperability safe harbor, and are interested in comments on those same issues as they might relate to a post-interoperability safe harbor."

HIMSS appreciates the complexity of this item given the many concerns regarding the method of defining an economic cap. HIMSS recommends the proposed regulation contain no capitation; however, if caps are used, the Department needs to take into consideration the following negative impact on the market and providers, in particular,

1. A cap could set the price indirectly;

2. Any cap would need to cover not just the hardware, but the connection, software, support and other related service for eRx and EHR;
3. eRx and EHR are two significantly different price points;
4. The manager of the service needs to be defined (hospital, other provider, etc.)

Ultimately, the challenge is that many products on the market are integrated, so a cap becomes very difficult to set. Perhaps the Department should consider identifying a scaled incentive period where donation levels would be at their greatest level early in the implementation process, and would steadily decrease over the course of 12-24 months. If providers know the donation parameters going into the process, they can make financial and budgetary decisions accordingly.

HIMSS has additional concerns for the Department to consider.

First, the Department should consider clearly defining the scope and length of coverage for training and support services. Left to the market, the level of training and support services could become a selling point that has unintentional impact on the intent of the safe harbor.

Second, by limiting donations to E-Prescribing systems only would adversely impact vendor products that offer integrated EHR systems, which would not be covered under the safe harbor as currently written. HIMSS strongly encourages the Department to review this section of the proposed regulations to consider a modification that would allow vendors with integrated EHR systems to compete in the marketplace with the same level of safe harbor.

Third, HIMSS encourages the Department to consider measures to protect providers and smaller facilities from being locked out of the market by more robust information systems offices at larger hospitals that will be able to use economies of scale to offer more robust services and response times that smaller facilities can not compete against.

22. OIG/CMS ask 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.

OIG: (Federal Register page 59024): We are interested in comments on the overall approach outlined above and how the various conditions might be crafted to ensure that the safe harbor conditions, taken as a whole, provide sufficient protection against fraud and abuse."

The evidence of lack of provider adoption requires the need for regulation, and demonstrates that electronic health record and E-Prescribing technology has little value to Recipients. Studies have demonstrated that Recipients value services more when a portion of the cost of care/service is shared. HIMSS suggests the Department require a minimal provider contribution for the purchase of wireless internet access.

HIMSS asks the Department to acknowledge stakeholder concerns that providers with an existing electronic health record or E-Prescribing 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

Concluding Remarks

HIMSS appreciates the effort the Office of the Inspector General and the Centers for Medicare and Medicaid Services has put forth in promulgating the proposed regulations. In order for the U.S. to

incorporate healthcare information technology solutions into efforts to improve patient safety and healthcare quality and contain costs of healthcare delivery, barriers to adoption must be overcome.

Additionally, the benefits associated with quality monitoring, healthcare delivery improvement and value-based purchasing are more difficult to achieve without healthcare IT. These important initiatives have the potential of making a large scale improvement in the delivery of healthcare in the United States. However, without widespread adoption of healthcare IT solutions humming in the background; providing responsible and timely clinical decision support to clinicians while collecting the necessary data for quality reporting efforts, these initiatives – and their collective impact – on healthcare will remain out of reach.

As proposed, the regulations address the first barrier to widespread adoption by fostering a more collaborative environment where healthcare IT community can support clinician adoption of E-Prescribing and EHR solutions. Stark Regulations and the Anti-Kickback Act are among the most referenced reasons why these collaborations remain at a small percentage of the healthcare market. It is our sincere belief that the exceptions and safe harbors identified in these proposed regulations provide the framework for responsible steps to begin the necessary widespread adoption of health IT solutions that will drive improvements and achieve the patient safety, healthcare quality and cost containment milestones.

In summary, HIMSS recommends the following Anti-Kickback Act and Stark regulation exceptions for E-Prescribing and Electronic Health Records:

- Replace the notional capitation ceilings with a graduated process that allows for higher volume donations early in the process and has set start dates for providers to enter into contractual agreements that moves the relationship from a donor-recipient to a financial exchange
- Consider broadening the list of donors and recipients to allow for a greater number of scenarios for encouraging HIT adoption
- Align interoperability and standards setting efforts with ongoing federal and private sector initiatives, including the Standards Harmonization and Certification Commission for Health IT contracts, and the Integrating the Healthcare Enterprise Initiative
- Enable clinicians to use a common tool for tasks to streamline workflow, encourage IT usage, and thus improve patient safety and healthcare quality
- Incorporate process with the national efforts to streamline biosurveillance and response and disaster management initiatives
- Grant EHRs and E-Prescribing technologies equal exceptions and safe harbors to maintain a level competitive environment in the marketplace.

Further, HIMSS suggests the OIG and CMS encourage a broad scope to the proposed rules that take into account the unique differences between the needs of ambulatory practices and hospitals. As it is well-documented, the workflow and information needs of office-based clinicians are fundamentally different than those of hospital-based clinicians.

Finally, HIMSS 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 an open, transparent RFP process typically used in government-sponsored tenders. 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 provides a safeguard against lock-in by the donating entity.

We look forward to the opportunity to discuss these perspectives at a time in the near future. We can provide subject-matter experts at any time in OIG's and CMS' review of this material. Please do not hesitate to contact us through Mr. Tom Leary, Director of Federal Affairs, at 703.834.9814 or tleary@himss.org.

Submitter : **Mr. Thomas Smith** **Date: 12/12/2005**

Organization : **Evanston Northwestern Healthcare**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

Issue

Background

Comments to Office of Inspector General
RIN 0991-AB39
Comments on Anti Kickback Statute Regulations

CMS-1303-P-44-Attach-1.DOC

EVANSTON
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Information Systems

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December 14, 2005

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

Proposed Regulation at 42 CFR Part 1001
Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute

On behalf of Evanston Northwestern Healthcare, we endorse the comments to the proposed regulation in question as submitted by The National Alliance for Health Information Technology. The recommendations made in the Alliance comment letter submitted to OIG dated December 8, 2005, reflect a consensus view in the healthcare field that the regulation as written will not achieve the intended effect of promoting the widespread adoption of health information technology and its productive use by America's physicians.

The Alliance's comments knowledgeably explain the impact and likely reception to the proposed regulation by the physician community and by those hospital organizations that are capable and willing to support the desire of physicians to provide better, safer and more efficient care for their patients. Remedies to the unintended inhibiting effects of the proposal regulation are necessary; these changes are important to the interests of both the healthcare industry and the Department of Health and Human Services in accelerating the acceptance of information technology and the interoperable exchange of patients' medical information among health care providers.

Health care IT offers the potential to dramatically reduce medical errors and enhance the efficiency of medical care by providing clinical support at the point of care in physician offices and hospitals. The potential savings are tremendous in both human lives and Medicare resources. But this promise can only be achieved if physicians participate fully and continually in the public-private sector campaign to provide the means for employing interoperable electronic health records. We appeal to OIG to reconsider its proposed regulation and strike a balance in the Anti Kickback Statute that truly advances this national goal

Sincerely,

Jeffrey H. Hillebrand
Chief Operating Officer

Thomas W. Smith
Chief Information Officer

Submitter : **Ms. Tracey Moorhead** **Date: 12/12/2005**

Organization : **DMAA**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1303-P-45-Attach-1.WPD

DMAA

Disease Management Association of America

December 12, 2005

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

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

To whom it may concern:

The Disease Management Association of America (DMAA) appreciates the opportunity to provide comments on the proposed rule to establish new exceptions to the physician self-referral prohibition in Section 1877 of the Social Security Act. DMAA strongly supports the Administration's goal to encourage widespread adoption of health information technology for the purpose of improving the quality and efficiency of health care.

DMAA

DMAA is a non-profit voluntary membership association representing all stake-holders in the disease management industry through public and private advocacy targeting the healthcare industry, government agencies, employers, and the general public in an effort to educate them on the important role disease management and care coordination programs play in improving healthcare quality and outcomes for persons with chronic conditions.

DMAA's more than 140 members include disease management organizations, health plans, employers, physician groups, hospitals, disease management support service providers, pharmacy benefit managers, pharmaceutical manufacturers, and disease management consultants. DMAA also has over 40 individual members, including individual health care professionals, academicians and other industry thought leaders, who join DMAA to access industry information and to participate in industry advocacy efforts.

Disease management is a system of coordinated healthcare interventions and communications for populations with conditions in which patient self-care efforts are significant. *Disease management supports the physician or practitioner/patient relationship and plan of care, emphasizes prevention of exacerbations and complications utilizing evidence-based practice guidelines and patient empowerment strategies, and evaluates clinical, humanistic, and economic outcomes on an on-going basis with the goal of improving overall health.* DMAA promotes population health improvement through disease and care management by: standardizing definitions and outcomes measures; promoting high quality standards for disease management and care coordination programs; and identifying and sharing best practices of program components.

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General Comments

DMAA supports the purpose of Section 1877 of the Social Security Act, the so-called "Stark Law", to prohibit physicians from making referrals to entities for certain designated health services paid by Medicare if they physician or an immediate family member has a financial relationship with that entity. The proposed rule addressed in these comments would create exceptions in the physician self-referral law to allow hospitals and other entities to donate information technology to physicians.

The disease management industry and discipline are rooted in the notion that systemic improvements in management of information are crucial to improving the quality of health care for patients with chronic disease and decreasing costs of their care. The U.S. Congress, in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) and The Department of Health and Human Services have both recognized this need for improvement in the interoperability, availability and deployment of healthcare information technology.

DMAA commends CMS and the Administration for seeking to encourage the adoption of these technologies. However, our members are concerned that the proposed rule does not advance the key objects of interoperability and may ultimately inhibit the widespread adoption of health information technology by imposing severe restrictions on both permissible donors and permitted technologies.

Specific Comments

1) Electronic Prescribing Exception: Section 411.357(v):

"Used Solely": The proposed rule requires that donated items and services must be "necessary and used solely" to send and receive electronic prescription drug information. CMS is concerned that physicians might intentionally divest themselves of functionally or technically equivalent items and services they already possess to shift the cost to donating entities.

However, CMS proposes to use its regulatory authority under section 1877 (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.

> **DMAA Recommendation**: DMAA commends CMS for its recognition that most users will prefer a single, multi-functional device, rather than many single-use devices. DMAA is concerned, however, that CMS seeks to qualify such multi-functional devices by requiring that they be "substantially" devoted to e-prescribing technologies. DMAA members believe that devices capable of e-prescribing technology, in addition to other functionalities, should be protected by this exception.
>
> As such, HHS should use its discretionary authority to provide an exception for multi-functional technologies, provided that at least one of the functions of that technology is to receive and transmit e-prescribing transactions. DMAA believes that such an exception will further stimulate adoption of health information technology, including electronic health records.

2) Electronic Prescribing Exception: Section 411.357 (v); Electronic Health Records Items and Services that are not certified: Section 411.357(w); and Certified Electronic Health Records Items and Services: Section 411.357(x)

Permissible Donors: The proposed rule identifies specific entities that may be exempt from providing items and services without violating the underlying Stark regulations. They are limited to: 1) hospitals and their medical staffs; 2) group practices and their physician members; 3) prescription drug plan sponsors to their physicians; and 4) Medicare Advantage organizations to their physicians. In the preamble, CMS states that it does "not believe that providers and suppliers of ancillary services, such as laboratories, are well positioned to advance the goal of widespread use of interoperable electronic health records for patients, nor would they have the same interest in doing so."

> **DMAA Recommendation:** Organizations providing population health management services have an interest in promoting and advancing the widespread use of interoperable electronic health records for patients and should be included in the list of permissible donors. Disease and care management programs and services provide coordinated healthcare interventions and communications for patients with chronic conditions in support of the physician/provider-patient relationship. Physician/provider electronic communication promotes the coordinated care efforts with exchange of treatment plans, patient education and compliance/outcomes measures. These programs and services utilize advanced HIT technologies and the widespread use of electronic health records would further improve the care of populations with chronic conditions.
>
> As such, DMAA recommends that HHS use its discretionary authority to promote the advancement and adoption of electronic health records to assist in the care of these chronic populations by exempting entities such as disease and care management organizations.

We appreciate the opportunity to provide these comments, and look forward to working with the Administration to promote the rapid adoption of health information technology for the benefit of all participants in the health care delivery system. Please do not hesitate to contact me if you have any questions about DMAA's comments on these proposed regulations.

Sincerely,

Tracey Moorhead
Executive Director

Submitter : **Mrs. Alissa Fox** **Date: 12/12/2005**

Organization : **Blue Cross and Blue Shield Association**

Category : **Health Plan or Association**

Issue Areas/Comments

Issue

Background

Attention: RIN 0991?AB39

RE: Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute

PLEASSE SEE ATTACHMENT

CMS-1303-P-46-Attach-1.PDF

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

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December 12, 2005

The Honorable Mark McClellan, MD, Ph.D.
Administrator
The Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Room 445-G
Washington, D.C. 20201

Attention: **CMS-1303-P**

RE: Comments on 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" NPRM CMS-303-P (42 C.F.R. Part 411) (70 Fed. Reg. 59182, October 11, 2005) CMS-1303-P

Dear Dr. McClellan:

The Blue Cross and Blue Shield Association (BCBSA) appreciates the opportunity to offer the attached comments on the Proposed Rule to establish exceptions to the physician self-referral prohibition (Stark) statute that would protect the donation of electronic prescribing and electronic health record (EHR) technology. BCBSA is made up of 39 independent, locally operated Blue Cross and Blue Shield companies that collectively provide healthcare coverage for more than 93 million people – nearly one-in-three – Americans. Many BCBSA companies will provide Medicare Part D benefits as Prescription Drug Plans (PDP) and Medicare Advantage organizations.

BCBSA strongly supports the adoption of health information technology, including electronic prescribing systems, to improve patient safety and the cost effectiveness of healthcare delivery. E-prescribing can improve the health and well-being of Medicare beneficiaries – and also help slow the rate of growth in spending – by reducing errors, increasing formulary compliance, and streamlining communications between physicians and pharmacies. Our attached comments are intended to help you make e-prescribing administratively practicable for providers, pharmacies and payers under Medicare Part D.

We would like to highlight two issues of particular concern to our member Plans:

- First, prohibiting PDPs and MA organizations from considering the volume and value of prescriptions that are paid for by the donor will have a chilling effect on donations *that are already taking place today.* A number of Blue Cross and Blue Shield Plans currently take a cost-effective approach to promoting electronic prescribing by targeting donations to physicians with the highest volume of prescriptions. BCBSA recommends that the rule eliminate this limitation for sponsors of PDPs and MA organizations.

- Second, creating a separate "pre-interoperability" and "post-interoperability" exception will discourage, not promote, the adoption of interoperable health information technology. Such a distinction is not necessary in light of the government's current initiatives to harmonize and certify interoperability standards.

We appreciate the opportunity to offer these comments, which we believe will make e-prescribing administratively practicable for providers, pharmacies and claims administrators, thus strengthening the overall Part D benefit.

We look forward to continuing to work with you and your staff on this and all other issues relating to the Medicare Prescription Drug Benefit.

Sincerely,

Alissa Fox

Alissa Fox
Vice President, Legislative and Regulatory Policy

Attachment

Submitter : **Ms. Ann Berkey** **Date: 12/12/2005**

Organization : **McKesson Corporation**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment - McKesson's E-Prescribing Comments

CMS-1303-P-47-Attach-1.DOC

McKesson Corporation
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San Francisco, CA 94104-5296

McKESSON
Empowering Healthcare

December 12, 2005

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

Attention: CMS-1303-P

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

Dear Dr. McClellan:

On behalf of McKesson Corporation (hereinafter "McKesson"), we are pleased to comment on the proposed rule issued by the Centers for Medicare and Medicaid Services ("CMS"), which would provide exceptions from self-referral regulations for electronic prescribing services and electronic health records ("EHRs"). Concurrently, we are filing comments to the proposed rule issued by the Office of Inspector General, which would provide safe harbors from the anti-kickback statutes for electronic prescribing services and EHRs.

As a Fortune 15 corporation dedicated to providing information technology, care management services, automation, medical supplies and pharmaceutical products to virtually every segment of the healthcare industry, we understand the challenges as well as the opportunity for significant quality and efficiency improvements through the widespread adoption of electronic prescribing. McKesson touches the lives of over 100 million patients in healthcare settings that include more than 5,000 hospitals, 150,000 physician practices, 10,000 extended care facilities, 700 home care agencies, and 25,000 retail pharmacies.

McKesson has established a strong record of support and involvement in important federal and state health initiatives. We have been a pioneer in the introduction of drug savings cards to help lower the costs of pharmaceuticals through our administration of the successful Together Rx™ card and our subsequent introduction of the CMS-endorsed Rx

Savings Access™ Card. The Together Rx™ card has delivered over $600 million in savings since June 2002 to more than 1.5 million low-income seniors. McKesson's Rx Savings Access™ Card is providing Medicare beneficiaries with an average savings of 15-25% on the most commonly prescribed medicines and is accepted by over 95% of pharmacies nationwide. To date, more than 236,000 Medicare-eligible seniors are enrolled in this card and have realized over $62 million in savings on their prescription drugs.

McKesson has also taken a proactive approach to providing disease management programs for commercial, Medicaid and Medicare populations where we leverage our experience with patient services, pharmacy management and healthcare quality improvement activities. In nine states where we provide disease management services to Medicaid patients, we estimate those states are saving approximately two dollars for every dollar spent with McKesson, while improving both the health status of the patient population and physician satisfaction with the program. Late last year, we were awarded one of the Chronic Care Improvement Program (CCIP) demonstration projects by CMS for Medicare beneficiaries.

McKesson has been delivering core medication safety and EHR components for more than a decade, including discrete data captured in the longitudinal – or lifetime – patient health record, medical images, document images, and the patient profile data needed for safe, effective office-based care. McKesson offers complete EHR solutions that automate and connect the acute and ambulatory care settings to provide a patient-centric view of clinical information. Today, McKesson's systems enable health care providers to write over one million electronic prescriptions annually and review test results, diagnostic images and other information needed for effective decision-making via secure web access. With our technology, providers are also scanning 62 million bar-coded medications annually, which trigger nearly 500,000 alerts weekly and prevent 96,000 medication errors each week.

We are drawing on our extensive experience in health information technology to share our perspective and provide comments on these proposed regulations.

Background

McKesson supports the efforts of the Department of Health and Human Services and CMS to reach the President's goal that every American should have an EHR within the next decade. We fully support this goal and believe that the implementation of proven high-impact, high-value health information technology ("IT"), coupled with the development of safe, secure interoperability standards for information sharing, will reduce medication errors, lower costs, and improve the quality and efficiency of healthcare. However, to realize all of the benefits, EHR technology must be adopted broadly.

While deployment of health IT is growing, the relative adoption rate of true electronic prescribing in physician practices can be measured in the single digits. Using the generally accepted six-level definition of true electronic prescribing, as published by the

e-Health Initiative in its 2004 report "Electronic Prescribing: Toward Maximum Value and Rapid Adoption", electronic prescriptions make up fewer than 5% of all prescriptions written in the United States. Additionally, according to the 2005 survey conducted by the Medical Group Management Association ("MGMA") Center for Research and the University of Minnesota, School of Public Health, EHR adoption by larger medical groups (those with over 21 physicians) has reached 19.5%, although adoption rates for smaller practices decreases significantly with practice size.

Two significant obstacles to health IT adoption are funding and the fear of prosecution under section 1877 of the Social Security Act, also known as the "Stark Law," or under anti-kickback laws.

- From a funding standpoint, many physician practices do not have access to sufficient capital or human resources to support technology investment. Physicians also believe they should not be the sole funding source for this technology, since other stakeholders benefit significantly from the physicians' investment in and utilization of that technology.

- Physicians and hospitals are hesitant to enter into technology agreements for fear of prosecution under the Stark Law or under anti-kickback laws. These laws prohibit exchanges that financially benefit physicians as a result of referrals or inducements to over-utilize Medicare or other government health care programs.

Together, these two barriers lead to uneven adoption of health IT rather than widespread deployment. For example:

> One McKesson hospital customer deployed an ambulatory EHR and electronic prescribing system for 130 physicians and medical providers dispersed across 30 locations in Central Illinois. Through electronic prescribing, physicians are now entering 35,000 electronic prescriptions per month, and patient information is available electronically regardless of location. Nurses and physicians spend far less time on medication management and have reduced chart requests and retrievals by over 90%, thereby greatly improving efficiency. Additionally, the broader EHR deployment has produced over $300,000 per year savings from reduced medical transcription costs, and vital patient information is now available across all settings of care for medical staff reference, resulting in safer, more efficient care. This successful demonstration of the quality and efficiency benefits of health IT has occurred only among the physicians that are employed in practices owned and managed by this hospital. Due to concerns about the Stark Law, the hospital decided it was too risky to connect an additional 350 community physicians who were on the medical staff but who practice independently from the hospital.

McKesson strongly supports the purpose and full enforcement of the Stark and anti-kickback laws; there should be no tolerance for fraud and abuse. McKesson also supports CMS' intent to create safe harbors for the funding of health IT systems for physicians and other clinicians by the proposed rules to the anti-kickback and physician self-referral laws under Medicare. Adoption of Stark Law exceptions and safe harbors is an important step in removing barriers to the deployment of proven technologies that reduce medical errors in order to save lives, improve the quality of care, and reduce costs.

We recommend that the proposed rule be modified to recognize that electronic prescribing is only part of EHR adoption, which, in turn, is only part of a larger integrated clinical work process. Additionally, any final rules should provide flexibility in implementation, as electronic prescribing and EHR solutions vary from hospital to hospital and physician to physician.

McKesson believes that electronic prescribing should be viewed in the context of these two important concepts:

Adoption of Electronic Prescribing Is a Vital First Step toward a Comprehensive EHR

We fully support CMS' objective to encourage the adoption of electronic prescribing. However, we strongly believe that electronic prescribing technology must be viewed as part of a much more powerful, effective and integrated EHR. In every implementation of McKesson's comprehensive EHR, physicians have chosen to employ the electronic prescribing applications as their first step in automating clinical processes. However, to fully achieve the promise of higher quality, safer, more efficient and cost-effective healthcare, we must equip physicians and clinicians with *all* of the information management tools needed to make informed decisions about patient care.

McKesson has found that the real value to a practice comes when the implementation combines e-prescribing with secure web-based access to patient information, including laboratory results, the patient's medical record, and diagnostic images. These solutions enable physicians to streamline their practice workflows and achieve dramatic financial and quality improvements. Further, few physicians choose to implement electronic prescribing without considering how that initial investment of staff, capital, and time can be leveraged to transform their clinical practice and their relationship with their patients.

Today, innovative hospitals and physician groups that deploy these technologies are saving lives and saving money. While making healthcare safer through seamless, rapid and accurate information flow, they are also addressing one-third of healthcare's overall costs: administrative paperwork, clinical errors, manual hand-offs and rework. As a specific example, McKesson has deployed an ambulatory EHR and electronic prescribing system in a mid-western medical group practice with 140 physicians and medical providers that represent 30 specialties dispersed across 14 locations in three states. Physicians are already entering 30,000 e-prescriptions per month, and patient information is available electronically regardless of location. Nurses spend far less time on medication management; they have reduced the time spent on paper charting activities by

24% and they are able to spend 16% more time with patients and families. In addition to improved quality and better decision making, physician shareholders in this group practice anticipate more than $5 million in savings over the next four years to offset their investment of financial and staff resources.

Investment in Electronic Prescribing Creates Value for All Healthcare Stakeholders

Under the provisions of the Medicare Modernization Act, CMS was granted the authority to create ways to support and accelerate health IT adoption. McKesson applauds the proposed rule's focus on health IT adoption and the agency's efforts to broaden the definition of health IT to include EHRs. We encourage the agency to apply an equally broad definition to the value derived from the successful deployment of health IT. We are concerned that the proposed safe harbor seeks to minimize the value of the "donation" by the hospital to the physician in order to limit the potential for abuse. We would prefer that the proposed rule minimize the regulatory burden on the donor (or funding organization) and the recipient to maximize the potential for adoption, and thus value, to all stakeholders.

Since no value can be derived from electronic prescribing without physician adoption, McKesson believes that it is very important that the safe harbor exemption should focus on ensuring that all necessary components of the electronic prescribing solution, such as hardware, software, services and connectivity, can be legally provided and fully funded. Restrictions on functionality, packaging or cost serve as a powerful disincentive to both potential funding sources and potential recipients. By recognizing that the physician is often a skeptical and reluctant participant in the implementation of technology, rather than viewing the physician solely as the beneficiary of an expensive gift, CMS will improve the likelihood that hospitals and recipient physician practices will participate in this opportunity to increase the broad adoption of health IT.

Specific Recommendations to Proposed Rule
Electronic Prescribing Exception: § 411.357(v)

Protected Non-Monetary Remuneration
We consider the technology "necessary" to ensure electronic prescribing adoption to include hardware, software, software maintenance, implementation and support services, and connectivity, including network infrastructure, the network itself, and any software necessary to provide access. The definition of "necessary" technology should be comprehensive since all of these elements are required to make a solution operational, productive and secure. At the same time, McKesson encourages CMS to avoid prescribed specifications of a delivery model, platform or technology for electronic prescribing.

McKesson believes the proposed recipient certification process may discourage physicians and funding organizations from participation, and, therefore, should be revised. We would suggest that any recipient certification be direct, simple and non-technical. The focus of the certification should be on broadly defined applications or

functionality – such as "stand-alone e-Prescribing system" – that can easily be interpreted and affirmed by a practicing clinician who has little or no technical sophistication. As currently written, the proposed rules require too much detail and knowledge of technology on the part of the typically practicing physician.

As CMS stated in its "Background", there is greater value to be derived for all of healthcare's stakeholders in terms of efficiency and safety after electronic prescribing or EHR technology is implemented. Therefore, McKesson recommends that if the funded technology represents an increased benefit over any existing technology in place at the practice, it should be covered under the safe harbor exception.

McKesson believes that an electronic prescribing product integrated with an EHR is the preferred solution for clinical practice automation. Therefore, any technology "necessary" to facilitate electronic prescribing must also be "necessary" to assure the full adoption of an EHR. We believe that the provision of multi-use hardware and integrated software will ensure the proliferation of electronic prescribing as intended by CMS. Therefore, we recommend that electronic prescribing and EHR be considered together for any definition of "used solely" when applied to donated or funded technology.

Designated Health Services (DHS) Entities Protected by the Exception
McKesson acknowledges the requirement that CMS must address physician inducement concerns by crafting these safe harbors. However, we would encourage CMS to take a clear, outcomes-based approach to crafting the exclusion. The clear delineation of proscribed behavior or outcomes is essential to address both hospital concerns regarding funding health IT initiatives and physician concerns over accepting technology donations.

While clearly the proposed regulations would continue to limit safe harbors, an unintended consequence might be to restrict adoption of this technology only to physician users. We recommend that the proposed regulation should be amended so that hospitals can provide hardware and software to both staff and non-staff providers. This technology allows for the efficient sharing of medical information, thereby enhancing the quality of care received by patients.

Group practices are permitted under current regulations to provide technology to their shareholder physicians. To stimulate greater adoption of technology by physician group practices, McKesson recommends that all payors, including the government, adopt "pay for use" incentives, such as a flat fee, for implementation to stimulate utilization of electronic prescribing and other EHR technology within these organizations.

Promoting Compatibility and Interoperability
We recommend that any clinical automation solution include electronic prescribing as one part of a larger EHR solution. If that clinical automation solution is capable of promoting efficient and safe clinical care beyond electronic prescribing, McKesson strongly recommends that CMS extend the safe harbor and thereby encourage the adoption of those capabilities.

The definition of interoperability as written in the proposed regulations is acceptable, although we prefer the definition of interoperability advanced by the National Alliance for Healthcare Information Technology ("the Alliance"), which states:

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

Ultimately interoperability will be defined by the standards created and implemented by the healthcare industry. We acknowledge and endorse the multi-stakeholder approach taken by the Certification Commission for Healthcare Information Technology (CCHIT) and strongly recommend that any definition CMS proposes be consistent with the interoperability standards employed by CCHIT in its certification process.

Value of Protected Technology

McKesson appreciates CMS' concerns that unlimited donations of health IT could improperly influence physician referrals and lead to undesirable consequences. However, we believe that a cap on the dollar amount associated with the funded technology not only limits the donation, but also will restrict the potential value that could be realized by all stakeholders and create an impediment to adoption. As long as the funding organization makes the same technology available to all eligible recipients, does not condition the provision of technology on patient treatment, does not restrict patient or physician choice, and does not restrict the delivery or implementation of technology based upon utilization by the organization, we do not believe that a cap to further prevent fraud and abuse is necessary.

Additionally, any cap on the value of the protected technology creates an artificial market price for technology. If CMS restricts the value of the funded portion of the technology, other stakeholders will, based on market experience, take that to be the total value of the technology. For example, if CMS says that the cap is 70% of the total *cost* of the necessary technology, there is no evidence to suggest that any other funding source – physicians, payors, or patients – will pay for the remaining 30%. Therefore, we recommend that the value of the technology be defined by outcomes, including reduced costs, greater efficiencies and improved patient safety which result from technology adoption and utilization.

McKesson agrees that protected technology is not just a solution for Part D beneficiaries; it should be used for all patients for whom eligibility and formulary data are available. McKesson encourages CMS to continue to focus on standards that are consistent with industry efforts outside the Medicare and Medicaid programs.

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

We support CMS in its efforts to include comprehensive EHR functionality as a major component of the safe harbor exception. We believe that the provision of hardware and

related services is critical to the adoption of this important technology and recommend that CMS expand its definition of "necessary" technology to include the same provisions for EHR technology as CMS has proposed for electronic prescribing.

CMS has requested comments regarding the appropriate definition of "interoperability" and the manner in which standards for interoperable systems will be determined. McKesson recognizes three parallel efforts that can and should contribute to an operational definition. First, we recognize the ONCHIT-2 grant award to the CCHIT. CCHIT has published multi-year criteria to define essential standards for the functionality, reliability, security and interoperability of electronic health records. We strongly urge CMS to use the CCHIT certification process for determining interoperability. We anticipate that the efforts of the American Health Information Community, chaired by Secretary Leavitt, and the work product of the Healthcare Information Technology Standards Panel, which was awarded the ONCHIT-1 contract for healthcare standards harmonization, will be incorporated into the CCHIT criteria as soon as practically possible. McKesson urges CMS to reference these important external efforts in the final regulations. Failing to do so will create confusion in the health IT industry regarding appropriate interoperability definitions and standards and will impede the efforts to harmonize existing health IT standards.

We also recommend that covered technology exceptions include computerized provider order entry (CPOE) systems. CCHIT has included CPOE as "essential functionality" for EHR systems in their certification criteria. Because clinical practice involves a wide variety of related prescriptive orders, including imaging, procedures, referrals, laboratory testing, supply orders, and medication prescriptions, we recommend that any safe harbor for CPOE include all physician orders.

With respect to permissible Donors and Recipients, the proposed regulation recognizes monetary costs as the sole means of valuation for the transaction. This is only a part of the value derived by all parties. McKesson strongly recommends that the contribution model be broadened to recognize the value derived by additional parties, including the payor and the patient, which reflects their interests and their potential for contribution. We further urge expansion of the pool of funding organizations ("donors") to include other parties, such as employers, pharmaceutical companies and health plans, which would realize value from the adoption of technology. The inclusion of such parties in a collaborative organization could create a broader base of funding for technology and establish the basis for funding via community-based collaboratives such as Regional Health Information Organizations.

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

We believe that the ongoing certification processes as proposed by CCHIT are sufficient to define, evaluate and certify interoperability. We recommend that CMS also adopt CCHIT's requirements for functionality, reliability and security standards. Since this certification process will be operational by the spring of 2006, we believe this process should be recognized by CMS as the standard for EHR and electronic prescribing

systems. We also recommend that the definition of "covered technology" should include any software which will be certified by the Commission. McKesson is pleased to be an active participant in the development of these processes.

Conclusion

McKesson supports CMS in this important first step towards encouraging greater adoption of electronic prescribing and EHR systems. The broad adoption of these technologies will create greater efficiencies within the healthcare system, reduce healthcare costs and increase patient safety. We believe that implementation of electronic prescribing is the critical first step to broader health IT adoption.

Specifically, McKesson recommends that any final rule incorporate the following:

1. a recognition that electronic prescribing technology is one component of an integrated EHR;

2. an acknowledgement that adoption of electronic prescribing will lead to greater adoption of comprehensive EHRs;

3. the inclusion of all services necessary to implement comprehensive EHRs;

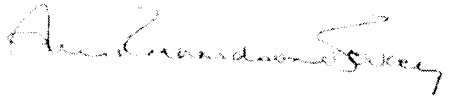
4. an emphasis on standards-based interoperability, which is key to insuring against proprietary abuse of the safe harbors; and

5. compatibility with interoperability standards adopted by existing standards harmonization and certification efforts.

McKesson appreciates the opportunity to share its views on the proposed electronic prescribing and EHR regulations. We commend the agency's efforts on this important initial step and its interest in receiving comments from the private sector. We look forward to working with CMS to implement the final rule and to address other important ways to promote the widespread adoption of electronic prescribing and health IT.

Should you have any questions on these comments, please contact me at 415.983.8494 or ann.berkey@mckesson.com.

Sincerely,



Ann Richardson Berkey
Vice President, Public Affairs

Submitter : Ms. Debra L. Ness **Date:** 12/12/2005

Organization : National Partnership for Women & Families

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1303-P-48-Attach-1.PDF

Comments on Centers for Medicare and Medicaid Services
Proposed Rules No. CMS-1303-P

As organizations representing a wide range of consumer interests, we are pleased to have the opportunity to comment on the proposed rule CMS-1303-P to create an exception to the physician self-referral prohibition in section 1877 of the Social Security Act. This rule addresses the donation to physicians of health information technology (HIT) to receive and transmit prescription drug information and/or for electronic health records software and training services. We recognize the potential of HIT to improve health care quality. Furthermore, we support efforts by the Department to promote the use of HIT by physicians and other health care providers, and are encouraged by the prospect of reduced errors and higher quality if e-prescribing is implemented. Below are our comments on the proposed rule.

Pre-interoperability Electronic Health Records Exception: §411.351(w)

This section would provide an exception to the Stark patient self-referral statute for donations of electronic health record technology made prior to the adoption of product certification criteria by the Secretary. We oppose this provision and recommend it be deleted entirely in the final regulations.

The Department is moving aggressively to put product certification criteria for ambulatory care in place in 2006. Promoting investment in this technology before DHHS adopts those criteria may seriously impede reaching the goal of a common platform – a goal which is part of the rationale for making this exception. Furthermore, allowing the exception to be in effect prior to certification could encourage providers and manufacturers to press for delay in adoption of the certification standards in order to avoid having to make new investments or to retain the market advantages they have created by installing their systems in physician offices. The Department should delay the effective date for the exception until the certification criteria are adopted.

Post-interoperability Electronic Health Records Exception: §411.357(x)

This segment of the proposed regulations would provide an exception to the Stark statute for donations of electronic health records software if the donation is made after the product certification criteria are adopted and if the software is compliant with the certification requirements. We support the intent of this exception but have some concerns about some of the text.

Subsection §411.357(x)(4) requires that neither the selection of the physician nor the amount or nature of the items and services donated can turn on the volume or value of

referrals or other business generated between donor and recipient. The section then enumerates six specific criteria that a donor might use that would be deemed compliant with the exception requirements:

1) total volume of prescriptions the recipient writes;
2) size of the medical practice;
3) number of hours the physician practices medicine;
4) extent of use of automated technology in the recipient's medical practice;
5) if the donor is a hospital, whether the physician is on its staff; or
6) another method that "is based on any reasonable and verifiable manner that is not directly related to the volume or value of referrals or other business generated between the parties."

This section is the heart of the proposed rule. The widespread adoption of EHR and EP technology can bring great benefits to patients, providers and insurers. Health information technology can help reduce medical errors, encourage patient activation and adherence to recommended regimens, and provide tools to evaluate clinical effectiveness, population health status, and the quality of medical care. The drive to promote the wider use of EHR and EP technology should not, however, trump the consumer protection or program integrity brought by the antifraud and abuse prohibitions. Donors should not be allowed to selectively fund physicians based on the volume of their prescribing, size of practice, or whether they are likely to be high users of technology since these could be proxies for the generation of referrals and revenue. We therefore recommend the following changes:

- Eliminate item #6, above. It is too open-ended and subjective and could become a major loophole.

- Our preference would be to require that donors offer the technology to all their physicians. In the case of hospitals that would be all physicians with privileges; for MCOs, all physicians in the MCO network; for group practices, all physicians in the group. In the case of an MCO, where it might be impractical to include all network participants, donors could be permitted to give priority to those physicians or clinics that have a certain percentage of their patients in the MCO. Similarly, for hospitals the alternative might be all physicians with privileges of a general category such as: a) practice privileges, or b) admitting privileges.

- Add a new exception that permits the donation to a physician or clinic that provides a certain level of uncompensated charity care or a combination of charity care and Medicaid patients. It is these providers – the community clinics, solo practitioners in rural communities or medically underserved areas – who are least likely to have the resources to make the health information technology investments on their own.

In the preamble to the proposed regulations the Department asks for comments on a cap on the value of the EHR donation, either a maximum percentage of the value of the

technology (which would require the physician to share the costs) or the lower of a fixed dollar amount or the percentage of value. We believe it would be hard to use a fixed dollar amount cap. The cost of technology will change over time and vary depending on the nature of the system. A cap on the percentage of the value of the technology being donated appears to be the more viable option. The physicians or clinics with high Medicaid and/or charity care caseloads should be exempted from cost-sharing.

Subsection 417.357(x)(9). This subsection requires that any donated EHR software contain electronic prescribing capability that complies with the electronic prescription drug program standards under Medicare Part D at the time the items and services are furnished. In the preamble the Department states that it "wants to ensure that integrated packages that could positively impact patient care are not excluded from the post-interoperability exception." We support the development of software in ways that promote avoidance of medical errors, improve quality of care, and/or enhance public health preparedness. It would be desirable that, as the Secretary adopts additional standards for EP, and for EMR systems, any donations qualifying for this exemption also have to comply with those standards without the necessity that the Department amend these regulations. We suggest the Department consider that possibility in shaping the final regulations.

Sunset section 411.357(x) entirely at a designated date. The rationale for allowing an exception to antifraud prohibitions decreases with the passage of time. Physicians may not purchase EHR technology now, but in the future having such technology will be a standard and necessary part of medical practice. At that point there will be no need for third parties to donate such technology. Furthermore, if interoperability becomes the norm, incompatibility across a network of providers ceases to be an issue. We therefore strongly urge that this entire section authorizing the Stark law exception for EHR be eliminated not later than five years from the date of publication of the final regulations. Alternatively, the sunset date could be delayed for up to two additional years if the Secretary makes an administrative finding that there is still a need for the exception to promote adoption of EHR technology.

While we support some limited exceptions to the physician self-referral prohibition for donation of EP and EHR technology, we believe these exceptions will have only a modest impact on the expansion of their use. Of much more importance are the standards harmonization and product certification efforts the Department already has underway. Equally important will be direct funding of loans and grants to states and providers and financial incentives for the adoption of HIT being incorporated in federally supported health care programs, including Medicare, Medicaid, FEHBP, TriCare, and SCHIP.

Thank you for considering our comments.

National Partnership for Women & Fa ilies
AFL-CIO
American Federation of State, Federa and Municipa Employees
Consumers Union
Department for Professional Employees, AFL-CIO
National Consumers League
Service Employees International Union

Submitter : Sabrina Allan
Organization : Pfizer, Inc.
Category : Drug Industry
Date: 12/12/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1303-P-49-Attach-1.PDF

Legal Division
Pfizer Inc
235 42nd Street
New York, NY 10017

December 12, 2005

By Electronic Mail

Honorable Mark B. McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1303-P
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 Administrator McClellan:

On behalf of Pfizer Inc. a research-based, global pharmaceutical company dedicated to the discovery and development of innovative medicines and treatments that improve the quality of life of people around the world, I am writing to comment on the Center for Medicare & Medicaid Services' proposed rule entitled "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements," see 70 Fed. Reg. 59,182 (Oct. 11, 2005) (the "Proposed Rule"). We appreciate this opportunity to comment on this important Proposed Rule, and looks forward to working with CMS to ensure that these provisions are implemented in a manner that reflects our concerns.

I. BACKGROUND

Pfizer has been very active in the policy debate surrounding health information technology. In 2004, we testified before the National Committee on Vital and Health Statistics regarding a number of specific policy and process concerns that were addressed in the Medicare Modernization Act of 2003 (MMA) regarding the potential for abuse of electronic prescribing technologies, including the use of such technologies as a platform for inappropriate commercial messaging. We presented that committee with examples of various behaviors, based on our experience with electronic prescribing vendors and technologies, demonstrating the risks of failing to address these issues. Pfizer also submitted comments to CMS as part of the

rulemaking process surrounding the new Medicare Part D outpatient prescription drug benefit that, while supporting the electronic prescribing program in general, again highlighted our policy and process concerns. As described below, while Pfizer is strongly supportive of the adoption of electronic prescribing and electronic health record (EHR) technology, we remain concerned that these technologies may be too costly for many physicians to acquire independently, resulting in slower adoption and delayed patient access to their benefits. Consequently, we support CMS's proposals regarding the exceptions to the physician self-referral law (Stark Law) for donations of electronic prescribing and EHR technologies to those practitioners in greatest need of these technologies. However, because we recognize the potential for abuse in these transactions, we also favor the implementation of adequate safeguards to prevent donors from leveraging their donations to provide incentives that may negatively influence the physician-patient relationship or otherwise adversely affect the provision of quality health care.

II. THE PROPOSED RULE

A. The Exceptions Should Require That Donated Technologies Present Information in a Neutral and Transparent Manner

To further the Stark Law's purpose of preventing fraud and abuse, the proposed exceptions should explicitly adopt standards requiring donated technology to present prescribing and other health data in a neutral and unbiased manner. In enacting the MMA, Congress was keenly aware of the potential threat that electronic prescribing technology poses to patient and physician autonomy. In particular, the MMA requires that electronic prescribing standards "allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems [to reduce medication errors, avoid adverse drug interactions, and improve medication use]." See 42 U.S.C. § 1395w-104(e)(3)(D). Similarly, the MMA Conference Report states that, under electronic prescribing, physicians should have access to "neutral and unbiased information on the full range of covered outpatient drugs," and that Congress did not intend for e-prescribing "to be used as a marketing platform or other mechanism to unduly influence the clinical decisions of physicians." H.R. Conf. Rep. No. 108-391, at 455-56. CMS also noted in the recently promulgated Final Rule on electronic prescribing standards that it has "concerns about how the provision of certain information [through e-prescribing] may unduly influence physician prescribing patterns." 70 Fed. Reg. 67,568, 67,583 (Nov. 7, 2005). As you are aware, it is precisely these non-clinical influences on physician decision-making that the Stark Law is intended to prevent.

Without standards prohibiting commercial messaging and requiring neutral presentation of information, donors of electronic prescribing and EHR technologies that are also payers may attempt to donate technology that, while otherwise satisfying the exceptions requirements, interferes with clinical decisions and injects financial incentives through the use of interruptive ("pop-up"), pre-emptive, and otherwise inappropriate messaging. We believe that physicians should be advised of all clinical and financial issues related to the writing of a prescription "up front" – that is, prior to making a decision – and such information should be presented in a passive, not interruptive, manner. Once a physician has made an informed selection, interruptive messaging should not be used to seek to change the physician's prescribing decision solely on the basis of financial considerations.

Similarly, we believe that "neutral and unbiased" presentation means that, when a physician prescribes a drug, she should be presented with all pertinent information at the beginning of the prescribing process, including the complete list of drugs used to treat a particular condition. This list can, of course, indicate which drugs are on-formulary preferred, on-formulary but not preferred, and entirely off-formulary. But physicians should not be shown only the preferred drug and then forced to click again to view non-preferred formulary choices, and perhaps have to click yet again to see off-formulary options.

Thus, to prevent donors from subverting the clinical decision-making process and steering physicians towards particular therapies or services, CMS should include in the exceptions a prohibition on inappropriate commercial messaging. This would be consistent with the intent of many of the exceptions promulgated under the Stark Law, i.e., prohibiting arrangements that appear likely to result in inappropriate, financially-based decision-making, while permitting transactions that present less substantial fraud and abuse risks and/or advance important public policy objectives. Further, to the extent that inappropriate messaging is the product of proprietary software and/or technology, interoperability of these technologies could be impeded unless such messaging is prohibited. Consequently, such conduct should be impermissible under the exceptions because it constitutes a substantial barrier to compatibility. Finally, technology that harasses the physician by attempting to persuade her to select a certain drug or service based on financial incentives, without considering the needs of the patient, not only interferes with the physician-patient relationship but could negatively affect the adoption of electronic prescribing and EHR technologies. If physicians become dissatisfied with a technology because of inappropriate commercial messaging, they may ultimately decide to discontinue its use.

Alternatively, CMS could address this problem by extending the exceptions to programs that offer recipients credits or "vouchers" for technology purchases. Under this type of program, the recipient would purchase the technology and submit appropriate documentation to the donor for reimbursement, thereby ensuring that any technology purchased through such a program otherwise met the requirements for an electronic prescribing or EHR donation. Providing the recipient a choice among products that are free of the donor's influence would help reduce potential abuse, while also ensuring that any donated technology met the standards required by law.

B. The Exceptions Should Not Artificially Limit the Value of Technology Donations

In the Proposed Rule, CMS states that it believes a monetary limit on the value of technology donations is appropriate to minimize the potential for fraud and abuse. See 70 Fed. Reg. at 59,186-87, 19,189. We recognize that CMS may have legitimate concerns that some donations of very costly technology are abusive. However, because the costs of obtaining "mainstream" electronic prescribing and EHR technologies are so difficult to ascertain at this time – the Proposed Rule seeks comment on this issue as well – establishing a rigid monetary cap could impede the adoption of these technologies if these costs ultimately wind up exceeding the cap. This may be particularly true for individual providers and small physician practices that cannot take advantage of the potential volume discounts to which larger providers may have access. For example, because of its purchasing power, a national hospital chain may be able to

obtain a lower cost technology system to donate to its physicians than a small local group practice.

If CMS establishes a cap, it is critical that the agency provide donors and recipients with a clear roadmap for establishing the value of the donation. If the process to calculate whether donated technology fits under the cap is unclear or complicated, donors and recipients may decide that the risk of accepting an excessive donation outweighs the benefit of obtaining the technology, thus slowing its adoption. We recommend basing the value of donations on the fair market value of the donated technology (as determined by a reasonable standard such as the donor's acquisition costs) because such a valuation would be the least burdensome to apply and would create the fewest impediments to technology adoption.

Finally, CMS may wish to consider implementing the exceptions initially without a cap, but then monitoring the industry reaction for possible abuse using its normal oversight protocols. If, after a reasonable period, CMS determines that the exceptions are being abused to the detriment of clinical decision-making and patient care, the agency could issue a new rule that would institute a cap on a prospective basis. At that point, it is likely that both industry and the government will have a better idea of the value of these technologies and the specific costs involved, and CMS will be in a better position to establish an appropriate process for determining a cap.

C. Certification Requirements Should Not Burden Technology Recipients

Under the Proposed Rule, recipients would be required to certify "that the items and services to be provided are not technically or functionally equivalent to items or services" the recipient already has. See id. at 59,185, 59,197-98. Given the dynamic nature of technology, it may be difficult for physicians and other recipients to ascertain whether the technology that is being donated is equivalent – technically or functionally – to technology the recipient currently possesses. Further, the Proposed Rule does not indicate who is to determine whether an upgrade "significantly enhance[s] the functionality of the item or service." Id. For recipients who are not technically sophisticated, minor changes may appear to be significant enhancements, which could place the recipient at risk if she makes the necessary certification to receive the donation. We are concerned that the uncertainty surrounding determinations of "equivalence" and "significance" may have a chilling effect on the dissemination of electronic prescribing and EHR technologies. Because one important purpose of the Stark Law exceptions is to provide certainty to affected entities that the conduct in question is lawful, we urge CMS to design any final certification requirement to address the potential burden of conducting technology evaluations prior to accepting a donation. In particular, we recommend that the exceptions expressly state that, so long as the recipient certifies in good faith and without fraudulent intent that the received technology is not technically or functionally equivalent to existing technologies, the transaction will not be stripped of protection if CMS subsequently finds that the donated and replaced technologies are equivalent.

D. Electronic Health Records Should Be Defined To Include Clinical Trial Data

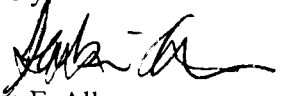
CMS is seeking comment on the definition of EHR. See id. at 59,188, 59,190. To fully realize the potential of electronic health information, all patient health records must be available in an electronic format, including clinical research records and other patient data that may be

accrued during a clinical trial. Therefore, it is important that the definition of EHR be broad enough to include clinical trial data, and that EHR technologies donated under the exceptions include the technologies used to capture and store such data.

III. CONCLUSION

We appreciate the opportunity to comment on these important issues raised by the Proposed Rule, and urge you to address these concerns in a manner that both fully protects the patient-physician relationship and furthers the goal of promoting the dissemination of health information technology. Please let us know if we can provide you with any additional information or other assistance.

Sincerely,



Sabrina E. Allan
Assistant General Counsel

Submitter : Mr. Carl Faulstick **Date:** 12/12/2005

Organization : Affiliated Healthcare Systems

Category : Laboratory Industry

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1303-P-50-Attach-1.DOC

Centers for Medicare & Medicaid Services
Re: CMS-1303-P; Solicitation of public comment

I encourage Centers for Medicare & Medicaid Services to include ordering of laboratory services in the proposed Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements.

I believe inclusion of lab services ordering in the Proposed Rule will impart advantages to all U.S. healthcare providers, payers and the general public. Laboratory service provider ability to provide equipment, software to referral sources will enable:

- Automation of interactive medical necessity guideline application to diagnostic laboratory test ordering. Software that automates and simplifies complex medical necessity guidelines that apply to lab test orders serve as an educational tool for extremely busy physicians and their office staff. Since physicians and other authorized providers are not medical coders or billers they are often unaware of the various nuances of narrative indications that effect test coverage and reimbursement. The absence of interactive software that alerts physicians and their office staff that a chosen narrative does not satisfy these guidelines often results in unnecessary Advance Beneficiary Notice (ABN) administration to patients and potential refusal of patients to have such tests performed because of the belief that they will bear the costs of these tests. Absence of such ordering software also increases the likelihood of unnecessary laboratory service claims denials, increased write-offs by hospitals and laboratories or subsequent time consuming telephone calls from laboratories to physician offices to obtain different diagnostic or symptom narratives.
- More consistent administration of ABN's by requiring physician office form administration to all Medicare beneficiaries before test orders can be accepted. Physicians have little or no motivation to purchase automated software that prints these forms for non-covered lab testing when they do not perform and bill for the tests. Absence of lab-provided software and equipment that perform this function result in inconsistent and arbitrary manual ABN administration so that some beneficiaries face the difficult choice of whether or not to having lab testing done because of expensive out-of-pocket costs while other beneficiaries are not forced to make this decision simply because their physician's office staff are less diligent in administering ABN's than other offices are. When less physician office staff diligence in ABN administration is exercised it is usually the laboratory performing the testing that bears the brunt of this failure by being forced to write off the charge(s).
- Decreased lab test order errors via the availability of laboratory provider complete test menu options to the physician. Manually completed teat requisitions are often a source of test order ambiguity and performance of diagnostic testing the physician did not intend but related to the laboratory in a less than specific manner. Test order errors have been identified as a potential compliance risk by the DHHS Office of Inspector General in the 1998 OIG Compliance Program Guidance for Clinical Laboratories. While labs that strive to maintain effective compliance programs make best efforts to reduce the risk of order errors, these risks are increased when physicians order laboratory testing using paper orders.

- Improved supply of patient Medicare Secondary Payer (MSP) information to hospitals and laboratories by physician offices. Electronic lab test ordering software that requires the provision of MSP information before a test order can be accepted can only help reduce the costs to hospitals and laboratories as well as federal and commercial healthcare program payers when instances of incorrect or incomplete MSP information is applied to healthcare claims.

While hospitals and laboratories bear the initial financial burdens due to the waste created by the problems identified above, these costs are inevitably passed on to and shared by federal and commercial payers, employers, consumers of healthcare services and the general public. In my opinion the costs incurred by these issues rival and likely surpass those laboratory-related problems identified in the preamble of the Proposed Rule.

In addition, while laboratory & hospital compliance officers understand CMS's concerns regarding gifts of fax machines and other equipment to referral sources expressed the preamble to the Proposed Rule, the assumptions underlying these concerns are not consistent with the realities of the provision of laboratory services in more sparsely-populated rural areas. As opposed to urban markets, reference laboratories that serve rural area referral sources often receive this business because of their geographical proximity to these referral sources. Dearth of competition in these rural markets is more likely due to the fact that other reference laboratories (both large & small) view investment in these markets as disadvantageous and not because the closer laboratory provides software and equipment as a reward for referral of services.

Since both the Stark Law and OIG Fraud Alerts previously allow for the provision of "non dual purpose" items and equipment (those items and equipment used solely for test ordering and collection of specimens for testing at the lab that provides the items, equipment, etc.) I hope that Centers for Medicare & Medicaid Services considers the confusion for lab service providers that will result if software and equipment that supports these services are not included in the Exceptions Proposed Rule. If lab service-related software is excluded from the Proposed Rule only those labs that strive to maintain effective compliance programs will be reluctant to invest in software and equipment that will likely reduce the costs and waste associated with problems defined above because of fear that acting otherwise will be construed as abusive or as an inducement for referral of laboratory test services.

Thank you for your consideration of my concerns in this matter.

Sincerely,

Carl Faulstick
Corporate Compliance Officer
Affiliated Healthcare Systems
Bangor, Maine 04401-4290
207-973-7649
cfaulstick@emh.org

Submitter : **Mrs. Alissa Fox** **Date: 12/12/2005**

Organization : **BlueC Cross and Blue Shield Association**

Category : **Health Plan or Association**

Issue Areas/Comments

Issue

Background

Attention: RIN 0991?AB39

RE: Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute
PLEASE SEE ATTACHMENT

Submitter : Roger Schwartz **Date:** 12/12/2005

Organization : National Association of Community Health Centers

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See attachment

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

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

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

Submitter :

Date: 12/12/2005

Organization :

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1303-P-53-Attach-1.DOC

Carin M. Cardinale
E-Mail: Carinc@hspm.com

December 12, 2005

VIA E-MAIL & FIRST CLASS MAIL
Attention: CMS-1303-P
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, Maryland 21244-8010

Re: **Proposed Exceptions to the Physician Self-Referral Law**

To Whom It May Concern:

Thank you for allowing us to comment on the proposed exceptions to the physician self-referral law. On behalf of the Blue Cross Blue Shield Association and Excellus Health Plan, Inc., our comments are as follows:

1. **Electronic Prescribing Exception: § 411.357(v).** §§ 411.357(V)(6) and (7) of the proposed exception would prohibit a donor PDP sponsor or MA organization from determining a recipient pharmacy, pharmacist or health care professional's eligibility, nor set the amount or nature of the items or services donated, in a manner that takes into account the volume or value of referrals or other business generated between the parties.

   Health plans necessarily consider the prescriptions they provide payment for when operating e-prescribing donation programs. In the private sector, a number of health plans promote e-prescribing and have created programs to donate e-prescribing hardware and software to physicians. These programs attempt to optimize the allocation of scarce resources by targeting physicians on the basis of volume. Health plans give donations to physicians who are writing a comparatively high number of paper prescriptions in order to have the most impact on improving physician prescribing habits and improve services provided to the most plan members.[1] Health plans end support to physicians who are not

[1] Health plans donate e-prescribing items to physicians with the expectation that the following efficiencies will be achieved:

- Promoting the use of generic prescriptions instead of identical and more expensive brand name prescriptions;

using the donated items. The proposed exception interferes with the ability of PDPs and MA organizations to donate e-Rx items in a manner that ensures the best efficiency and patient safety outcome for the Medicare program.

We recommend that CMS specifically allow sponsors of PDPs and MA organizations to determine eligibility or the amount or nature of the items and services in a manner that takes into account the number of prescriptions written by the recipient and paid by the PDP or MA organization. Concerns that compensation arrangements targeting high-volume physicians are an attempt to obtain referrals of services for the benefit of the donor do not apply to PDP and MA organizations. Unlike donors paid on a fee-for-service basis or whose program compensation is otherwise tied to volume increases, PDPs and MA organizations are paid on a capitated basis that places them at financial risk. Thus, PDPs and MA organizations share with CMS the desire to promote gains in efficiency and quality and to control fraud and abuse.

- **Electronic Prescribing Exception: § 411.357(v).** The proposed exception only applies to specific entities that may provide assistance to recipients. Specifically, proposed § 411.537(v)(1)(iii) would protect donations from PDPs and MA organizations to prescribing physicians.

An exception is necessary because outpatient drugs are a designated health service to which the physician self-referral prohibition law apples. The regulatory definition of outpatient drugs includes Medicare Part D and Part B covered drugs. It can be interpreted that plan-based e-prescribing donation programs are not covered by the exception if used to prescribe Medicare Part B covered outpatient drugs (e.g. those covered under a Medigap plan) because the health plan donors are limited to PDP sponsors and MA organizations. Since the exception would also require that the donated e-prescribing items be useable for all patients regardless of payor status, the prescriptions covered by Medicare Part B and other benefit plans is inevitable. Thus, a limited applicability interferes with achieving interoperability and impairs the exception's utility.

Accordingly, we recommend that the final rule clarify that all Medicare and Medicaid-covered drugs are excepted. This modification is consistent with the applicable scope of the e-prescribing standards as stated in the final interoperability standards rule. In that rule, CMS concluded that the standards would be most effective (and less difficult to apply and enforce) if made applicable to all Medicare covered drugs for Medicare covered individuals, and not just those enrolled in Part D. The physician self-referral exception should not conflict with or otherwise limit the scope of the agency's required standards.

- Increasing adherence to formulary specifications, which include quality of care considerations; and

- Reducing the number of telephone calls and other handling and administrative costs.

- **Electronic Prescribing Exception: § 411.357(v).** CMS proposes to place a cap on the value of donated protected technology and solicits comment on such issues as the amount of the cap and methodologies to determine the cap.

  It is our position that caps are inherently arbitrary. As CMS acknowledges, the cost of implementing an electronic prescribing program will not necessarily correlate with the amount of any cap if one is established. If set too low, a cap may impede upon the donation and acceptance of the technology. The greater the proportion of acquisition or follow-on operating costs outside the cap, the less inclined the physician would be to accept the donation.

  We recommend that CMS not place a financial cap on the aggregate fair market value of all items and services provided to a physician from a single donor. Any degree of fraud and abuse avoidance achieved by requiring proof that costs were within a given cap would not outweigh the administrative burden of collecting, maintaining, reporting, and auditing cost data on installation, maintenance and other related costs.

  The relative value of covered and non-covered costs is different for each arrangement. For example, connectivity or maintenance costs in urban settings are probably not a high value element of the fair market value of the donation, because of the ubiquitous nature of connectivity and maintenance resources in dense population areas. Conversely, limitations on connectivity availability or maintenance support for rural arrangements may mean that actual cost would have to be included. Including these costs lowers the amount available under the cap for the technology. The same is true for all regional cost-center variations and their relative fair market value. The pressure to include or exclude those costs in the arrangement will vary based on the recipient's tolerance for accepting those additional costs as part of accepting e-prescribing.

  Other safeguards that limit the potential financial benefit to the donor, such as interoperability requirements, and that limit the add-on value to the recipient, such as not duplicating technology the physician has already obtained, are sufficient deterrents to overly generous donations. This recommendation also applies to proposed caps on the donation of EHRs.

- **Pre-Interoperability Electronic Health Record Exceptions § 411.357(w)**. CMS specifically solicited comments addressing whether the pre-interoperability exception may promote closed systems that effectively tie physicians to particular providers and impede the spread of interoperable EHRs. To illustrate this concern, CMS gives as an example a hospital that donates expensive technology to a physician. The hospital may then exercise control over that physician sufficient to preclude or discourage other systems or health plans from having access to the physician for their own networks.

  Donations of technology can create captive relationships between donors and recipients. A pre-interoperability exception is inherently risky because it would facilitate such captive arrangements. Furthermore, permitting the donation of non-interoperable EHRs

may create pressure to allow continued use of those systems, even when new interoperable standards are adopted.[2]

Moreover, only three conditions distinguish the pre-interoperability exception from the post-interoperability exception:

- Post-interoperability donations may be multi-functional; pre-interoperability donations may not;
- Post-interoperability donations may have a cap that is greater than the cap on pre-interoperability donations; and
- Post-interoperability recipient eligibility may be based on certain types of volume, such as total written prescriptions; pre-interoperability donations may not;

The first two conditions are not truly distinguishable. Given the industry trend toward integrated clinical/administrative systems, the distinction in the first condition is archaic and may soon be rendered moot. For all practicable purposes, the second condition is without distinction, since any cap is not administratively feasible and will not increase the anti-fraud deterrence already provided by other safeguards in the exception.

We recommend that CMS not create separate pre- and post-interoperability exceptions for EHR system donations. While the adoption of standards and a certification process by the Secretary may be several years away, industry certified ambulatory EHRs may be available before CMS publishes the exception as a final rule. The Certification Commission on Health Information Technology (CCHIT) has issued its draft final certification criteria and process for an ambulatory EHR. CCHIT intends to begin certifying EHRs by March of 2006.

Any exception should require that the donated EHRs be based on acceptable industry standards of interoperability, even in the absence of a certification process or standards adopted by the Secretary. There should be one exception that ensures a recipient's ability to enter into or use the donated technologies in other relationships.

Additionally, § 411.357(w)(8) proposes to exclude multifunctional items and services, prohibiting the donation of any billing, scheduling, or other general office management or administration software or services. In the post-interoperability EHR exception, CMS states in the preamble that the scope of the covered software will expand and potentially include other kinds of software, provided that e-prescribing and EHRs are the core functions of the donated software. CMS believes that integrated packages could positively impact patient care may be appropriate to include in the post-interoperability exception. CMS requests specific comments on the type of software to protect under the

[2] This is in line with what we learned from the HIPAA Administrative Simplification experience with standard transactions.

exception, e.g., CPOE. Items used solely to conduct personal business or business unrelated to the medial practice would be excluded.

Two issues arise. First, while the preamble implies a broader donation capability, there is no specific language in the proposed post-interoperability exception. The silence creates an ambiguity. Second, physician office communication with health plans typically involves eligibility, coverage and payment issue. This communication may be a function of billing and general office management systems. Information pertinent to these communications will inevitably be located in the EHR. Movement of this information from the EHR through billing or office management systems to payers will become an essential element of an interoperable system. The emphasis on integrated packages that impact patient care, coupled with the CPOE example, does not specifically indicate that integrated physician office management software would be allowed.

We recommend that any EHR exception should contain specific language that will permit the donation of integrated software solutions. Such software should support the entire workflow in a physician's office that could benefit from the application of health information technology. We have already recommended that there be only one exception for interoperable EHRS.

The EHR exception should allow for software functions that facilitate the movement of pertinent information related to payment policies, coverage and utilization. This includes the capability of transferring EHR-based information to payers through billing and/or office management systems as necessary. The final rule should acknowledge the need for this capability so that the exception will not impede the adoption and use of health information technology. BCBSA encouraged the certification of this capability in EHRs in our comments to the Certification Commission on Health Information Technology (CCHIT) on its certification criteria and process.

Please do not hesitate to contact me with any questions regarding these comments.

Submitter : Dr. Robert Kirsner **Date:** 12/12/2005

Organization : American Academy of Dermatology Assn

Category : Physician

Issue Areas/Comments

Issue

Background

On behalf of the 14,000 members of the American Academy of Dermatology Association, we appreciate this opportunity to comment on the proposed rules creating terms and conditions governing both physician self-referral exceptions for certain electronic prescribing technology and electronic health records donation arrangements. The Academy supports the intent, direction, and objectives of the proposed exception rules in that they would further provide physicians, especially those in small and medium outpatient settings, including dermatologists, with a viable opportunity with which to pursue adoption and implementation of health information technology solutions.

We believe that the proposed rules should be flexible and practical enough to enhance the prospects of health information technology automation and promote greater adoption of health information technologies particularly for physicians in individual, small and medium-size practices currently at a disadvantage because of cost barriers and lack of technical know-how.

We have reservations with certain aspects of the current proposed rules, such as:

1. imposing restrictions or de-coupling the types of health IT hardware and software solutions that can be donated or transferred would prove counterproductive to individual and small practices and undermine the goal of a fully automated, integrated, and interoperable healthcare environment; and
2. because health IT costs remain unaffordable for many individual and small practices, any contemplated financial caps on donations of hardware, software, and support services should be scalable and in proportion to the needs to the recipient.

CMS-1303-P-54-Attach-1.DOC

American Academy of Dermatology Association

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December 12, 2005

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

RE: Proposed Rule: Physicians' Referrals to Health Care Entities With Which They Have Financial Relationship; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements – 42 CFR Parts 411 RIN 0938 – AN69

Dear CMS Representative:

On behalf of the 14,000 members of the American Academy of Dermatology Association, we appreciate this opportunity to comment on the proposed rules creating terms and conditions governing both physician self-referral exceptions for certain electronic prescribing technology and electronic health records donation arrangements. The Academy supports the intent, direction, and objectives of the proposed exception rules in that they would further provide physicians, especially those in small and medium outpatient settings, including dermatologists, with a viable opportunity with which to pursue adoption and implementation of health information technology solutions.

We believe that the proposed rules should be flexible and practical enough to enhance the prospects of health information technology automation and promote greater adoption of health information technologies particularly for physicians in individual, small and medium-size practices currently at a disadvantage because of cost barriers and lack of technical know-how.

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2. because health IT costs remain unaffordable for many individual and small practices, any contemplated financial caps on donations of hardware, software, and support services should be scalable and in proportion to the needs to the recipient.

Electronic Prescribing Exception: § 411.357 (v)

We applaud the Department's efforts in selecting electronic prescribing as the starting point in which to apply exceptions to the physician self-referral law in that electronic prescribing technology can serve as a critical first step when it comes to enabling physicians to migrate towards more robust health information technology solutions. The Academy agrees with the need to qualify such incentives whereby protection from the self-referral prohibition would allow physicians to receive donated hardware, software, broadband or wireless internet connectivity, training, IT support services specifically and necessary for purposes of conducting, transmitting, and receiving electronic prescribing information. Such delineation in the proposed exception can preempt any risk of misuse as well as fraud and abuse concerns.

Notwithstanding, we wish to advise that any attempt to implement a certification process verifying the legitimate needs of an individual physician in obtaining donated electronic prescribing technologies from a prospective donors (either a hospital, group practices, Medicare prescription drug plan, or a Medicare

Advantage managed care organization) be informed by a clearly defined and transparent set of criteria as well as easy to understand terms and conditions spelling out such a transfer. Furthermore, any donation or transfer of qualified electronic prescribing technology items, services, and upgrades should be based on both the receiving physicians' declaration of their technical needs and good faith compliance with any binding representation and warranty made to justify the donation certification process. As the proposed exception contemplates addressing both "substantial use" and imposing a potential dollar cap on the value of the electronic prescribing technology, we urge that a flexible and enlightened approach be adopted so as not to restrict donors from providing diminished incentives that would discourage small and medium size practices from enjoying regulatory relief. For instance, the bundling of other non-exempted technologies, such as practice management software, with electronic prescribing tools can be addressed by a carve-out rule that itemized and dictates the terms and conditions for adopting multi-functional health information solutions.

We agree that donation of electronic prescribing technologies should be limited to recipient physicians but that use of such items and services, once received, be available to their non-physician prescribing health care professional staff such as physician assistants and nurse practitioners. Moreover, group practices should be allowed to provide exempted technologies to their independently contracted physician members that are employed for purposes of providing medical care to patients.

Any dollar value ascribed to electronic prescribing technologies should take into account the current challenges and barriers faced by small and medium-size practices in adopting costly technologies. Therefore, a scalable formula favoring these small business entities should be made in order to boost incentives and reduce barriers. We support the Department's recognition that electronic prescribing technologies should and can be used to benefit all patients and not just insured and Medicare beneficiaries. When considering a formula to address financial caps, we urge the Department to draw on the practical experiences and lessons learned by private payers that have launched several state e-prescribing programs to jump-start adoptions at the local level. Their experiences should help the Department in developing a fair, equitable, and balanced cost-sharing solution that can benefit both the donating entity and the recipient party.

The inclusion of electronic health record technology in the proposed exception provisions would add further incentives for physicians who are interested in implementing but are unable to afford such costly technology. Indeed, such an addition will make the proposed exceptions to the self-referral prohibitions rules more attractive to physicians who are currently at a disadvantage in adopting health information technology automation and will benefit their patient population.

Pre-Interoperability Electronic Health Records Exception: § 411.357 (w)
Allowing exceptions to apply to electronic health records technology prior to the establishment of interoperable and product certification standards may be of limited value. In view of future efforts by the Department to adopt and implement such functional standards, we agree with the approach to limit and sunset such exceptions when electronic health records standards are finally in place. Absent restriction, this allowance would serve to confuse physicians by providing a false start with electronic health records adoption and would risk the prospect of having to re-adopt such technology later down the road.

Post-Interoperability Electronic Health Records Exception: § 411.357 (x)
We agree that only when interoperable standards and electronic health record product certification criteria are in place will benefits be readily available to patients and their physicians. There is strong evidence that both individual and small outpatient physician practices face a number of disadvantages in adopting and implementing health information technologies, particularly electronic health record systems. The Academy believes that the proposed electronic health records exception, eligibility and selection criteria should create more attractive incentives for these smaller medical practices, and should seek to remedy the particular challenges faced by rural-based medical offices. For example, any contemplated dollar caps on the transfer of either electronic prescribing or health records technology should factor in the needs of individual, small,

and rural practices, and should not restrict or penalize any support or maintenance service that is reasonable when using information technology devices and processes.

The Academy is confident that the proposed exceptions to the physician self-referral prohibitions will safeguard against the risks of fraud and abuse while providing physicians with an attractive path to adopting electronic prescribing and electronic health records technologies. The Academy continues to encourage both the public and private sectors to develop mechanisms that provide physicians with real incentives to adopt health information technologies.

We appreciate the opportunity to provide comments regarding this important physician self-referral exception provision. Thank you for reviewing these comments. If you have any questions regarding our recommendations, please contact Jayna Bonfini at jbonfini@aad.org at 202-712-2614, or William Brady at wbrady@aad.org or 847-240-1824.

Sincerely,

Robert Kirsner, MD, PhD
Chair, Practice Management Task Force

Cc: Clay J. Cockerell, MD, President, AADA
Stephen P. Stone, MD, President-Elect, AADA
David M. Pariser, MD, Secretary-Treasurer, AADA
Ronald A. Henrichs, CAE, Executive Director and CEO, AADA
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Sandra Peters, Senior Manager, Workforce, Insurance and Practice Issues, AADA
William Brady, Manager, Practice Management, AADA

Submitter : Roger Schwartz **Date:** 12/12/2005

Organization : NACHC

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1303-P-55-Attach-1.PDF

December 12, 2005

Dr. Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., S.W.
Washington, DC 20201

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

Dear Dr. McClellan:

The National Association of Community Health Care Centers, Inc. ("NACHC"), on behalf of more than 1,000 Federally Qualified Health Centers ("FQHCs"), submits these comments on the proposed regulation by the Centers for Medicare & Medicaid Services ("CMS") to provide an exception to the Stark physician self-referral ("Stark") law for certain electronic prescribing ("e-Prescribing) and electronic health records ("EHR") arrangements. We appreciate the opportunity to comment on the proposed rule.

Electronic Prescribing Exception: § 411.357(v)

Protected Entities

CMS requested comment on whether it should use its own authority under section 1877(b)(4) of the Social Security Act ("the Act") to protect qualifying e-Prescribing technology provided to physicians by other DHS entities. The proposed rule protects donations made by a group practice to its physician members.

We agree with CMS that the provision of e-Prescribing technology by a group to its members does not necessarily require a new exception because other exceptions would apply to protect those arrangements (e.g., in-office ancillary services exception, employment exception, personal services exception, and non-monetary compensation exception).

To the extent that CMS concludes, however, that a new exception is required to protect donations made by a group practice to its physician members, we believe that, in certain circumstances, the existing regulatory definition of "group practice" may not encompass FQHCs.

We therefore urge CMS to expand the covered entities within the proposed exception so that it protects donations made by an FQHC (as defined at 42 C.F.R. § 405.2401(b)) to physicians who provide services to patients of the FQHC.

Definition of "Necessary"

CMS requested comment on its interpretation that the term "necessary" excludes items or services that are technically or functionally equivalent to items that the receiving physician already possesses or services that the physician has already obtained. We believe that interpretation is unduly restrictive, inconsistent with the purpose of the exception, and will not achieve its intent.

In our view, the purpose of the term "necessary" in section 1860D-4(e)(6) of the Medicare Modernization Act ("MMA") was simply to ensure that the donated items and services are related to the transmission and receipt of electronic prescription information. Congress did not want e-Prescribing to be used as a "marketing platform or other mechanism to unduly influence the clinical decisions of physicians." H.R. Conf. Rep. No. 108-391, at 456 (2003).

CMS has interpreted "necessary", however, in a way that gives higher priority to the policy concerns of the Stark law than to the e-Prescribing exception explicitly directed by Congress under the MMA. Because of uncertainty in making the required technical comparisons, the proposed physician certification scheme proposed by CMS is likely to chill those donations altogether. This defeats the purpose of the e-Prescribing exception which is that it be rapidly adopted as a vehicle to reduce medical errors and to improve efficiencies in the health care system.

Although CMS recognizes that the donors of items and services will not necessarily know which items and services that the physician already possesses or has obtained, it also true that the physician recipient will not necessarily have the technical expertise to determine whether the items and services are technically or functionally equivalent to items or services that he or she already possesses or has already obtained. Because the physician will need to rely on the technical expertise of others, the certification scheme will become a mere formality.

We therefore urge CMS to broaden the definition of "necessary" to mean donated items and services that relate to the transmission and receipt of electronic prescription information.

Exceptions for Certain Arrangements involving Electronic Health Records Items and Services: § 411.357(w) and 411.357(x)

Covered Technology

In both exceptions, CMS proposes to protect only EHR software that is separate from and independent of related hardware, connectivity services, billing or scheduling software, or software that might be used by a physician to conduct personal business or business unrelated to the physician's medical practice. We believe that definition is too limited in scope and will not be practical for many rural health care providers (such as FQHCs).

The interoperable health information infrastructure that CMS seeks to promote under these exceptions requires more than software. It also requires hardware and connectivity, such as T1 lines and broadband connectivity, transmission interfaces, and secure connections. As CMS acknowledges, rural providers are more likely to lack sufficient hardware or connectivity

services to implement effective EHR systems.

In addition, CMS requires that the covered technology be "used solely" for the transmission, receipt, or maintenance of patients' EHRs. This would exclude technology that includes billing, computerized order entry (CPOE), or scheduling functions as well as decision-support tools such as a medical reference library and clinical practice protocols. Currently, some EHR systems on the market include these functions and tools and there will be a loss of potential efficiencies if the Stark exceptions force these functions to be carved out.

We therefore urge CMS to revise the definition of covered technology to include hardware, software, and connectivity services related to EHRs and not to require that the technology be used solely for the transmission, receipt, or maintenance of patents' EHRs.

Permissible Donors

In these two exceptions for EHR arrangements, CMS proposes to protect the same categories of donors and physicians as the proposed exception for e-Prescribing items and services. For the reasons described above in our comments on proposed § 411.357(v), we believe these exceptions should be broadened to protect donations from FQHCs to physicians who provide services to patients of the FQHC.

Definition of "Necessary"

In these two exceptions for EHR arrangements, CMS proposes to apply the same definition of "necessary" in these exceptions as it uses in the exception for e-Prescribing items and services. For the reasons described above in our comments on proposed § 411.357(v), we urge CMS to revise the definition of "necessary" to mean donated items and services that relate to EHR technology.

Conclusion

Congress and the President have determined that the electronic transmission of both drug prescriptions and health records of all patients will enhance the quality of their health care. In furtherance of this goal, we submit the above recommendations to the proposed rule for e-Prescribing and EHRs.

Again, thank you for the opportunity to submit these comments. Please do not hesitate to contact us at (202) 296-0158 if you have any questions.

Sincerely,

Roger Schwartz
Legislative Counsel and Director of State Affairs
National Association of Community Health Centers

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

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

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