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.

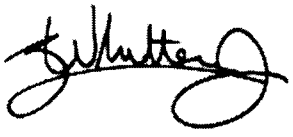
4. Pre-Emption of State Law.

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.

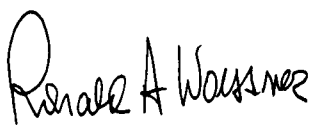
Electronic prescription services is a developing market and the data presently available is of scant predictive value because expectations regarding pricing and payment practices likely will evolve significantly over a short period. For example, we anticipate that there will be shifts in payment methodology 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.

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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- <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.

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

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President and CEO

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

Organization : **Regional Health, Inc.**

Category : **Hospital**

Issue Areas/Comments

GENERAL

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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.