



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 rule¹ (“**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 used² 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 results⁶
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 purposes⁸
6. Reviewing patient schedule⁹
7. Accessing/updating on-line medication administration records¹⁰
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)

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 technology¹¹ 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.

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 it 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

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 hosted¹⁸ software applications usually are priced on a subscription basis, subject to an annual or monthly fee.

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 than 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 standards¹⁹ 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

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

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.

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.

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 identified 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

A handwritten signature in black ink that reads "Ronald A. Woessner". The signature is written in a cursive, slightly slanted style.

Ronald A. Woessner
Senior Vice President and General Counsel