

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 411

[CMS-1303-P]

RIN 0938-AN69

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: As required by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), this proposed rule would create an exception to the physician self-referral prohibition in section 1877 of the Social Security Act (the 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. In addition, using our separate legal authority under section 1877(b)(4) of the Act, we are proposing two separate regulatory exceptions for electronic health records software and directly related training services. These exceptions are consistent with the President's goal of achieving widespread adoption of interoperable electronic health records for the purpose of improving the quality and efficiency of health care, while maintaining the levels of security and privacy that consumers expect.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 12, 2005.

ADDRESSES: In commenting, please refer to file code CMS-1303-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/regulations/ecomments>. (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address only: Centers

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

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address only: 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.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document. For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Linda Howard, (410) 786-5255.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code [CMS-1303-P] and the specific "issue identifier" that

precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. CMS posts all electronic comments received before the close of the comment period on its public Web site as soon as possible after they have been received. Hard copy comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

Open Door Forum: We are planning to schedule an Open Door Forum early in the comment period to discuss the benefits and risks of donating electronic prescribing and electronic health records technology. Please note, however, that our planned Open Door Forum is in addition to, and not in lieu of, the public comment process discussed above. To be assured consideration, please forward your written comments by the close of the comment period.

I. Background

[If you choose to comment on issues in this section, please include the caption "Background" at the beginning of your comment.]

Section 1877 of the Act, also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership interest or compensation arrangement), unless an exception applies; and (2) prohibits the entity from submitting claims to Medicare for those referred services, unless an exception applies. The statute establishes a number of exceptions and grants the Secretary the authority to create additional regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. When enacted in 1989, the physician self-referral law applied only to physician referrals for clinical laboratory services under Medicare when made to an entity with which the physician (or an immediate family member) had a financial relationship. In

1993 and 1994, the Congress expanded the prohibition to include ten additional DHS and added section 1903(s) of the Act, which extended aspects of the referral prohibition to the Medicaid program.

Section 1877 of the Act, as it applies to referrals for eleven DHS, has been in effect and subject to enforcement since January 1, 1995. On August 14, 1995, we published a final rule with comment period in the **Federal Register** (60 FR 41914) that incorporated into regulations the physician self-referral prohibition as it applied to clinical laboratory services. That final rule did not address the other DHS. On January 9, 1998, we published a proposed rule in the **Federal Register** (63 FR 1659) to revise the regulations to cover the additional DHS and the Medicaid expansion. On January 4, 2001, we published the "Phase I" final rule with comment period in the **Federal Register** (66 FR 856). Phase I addressed the general prohibition on physician self-referrals and the statutory exceptions applicable to both ownership and compensation arrangements, defined key terms, and created a number of new regulatory exceptions. With two exceptions, the regulations published in Phase I became effective on January 4, 2002.¹ On March 26, 2004, we published the "Phase II" interim final rule with comment period in the **Federal Register** (69 FR 16054), which became effective on July 26, 2004. Phase II addressed the statutory exceptions related to ownership and investment interests, the statutory exceptions for certain compensation arrangements, and the reporting requirements. Phase II also created some new regulatory exceptions and addressed public comments on Phase I.

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) added a new section 1860D to the Act establishing a prescription drug benefit in the Medicare program. As part of the new legislation, the Congress directed the Secretary in section 1860D–4(e)(4) of the Act to

adopt standards for electronic prescribing in connection with the new prescription drug benefit with the objective of improving patient safety, quality of care, and efficiency in the delivery of care. (H.R. Conf. Rep. No. 108–391, at 455, 456 (2003).) Section 1860D–4(e)(6) of the Act directs the Secretary, in consultation with the Attorney General, to create an exception to the physician self-referral prohibition and a safe harbor under the anti-kickback statute (section 1128B(b) of the Act) to protect certain arrangements involving the provision of non-monetary remuneration (consisting of items and services in the form of hardware, software, or information technology and training services) that is necessary and used solely to receive and transmit electronic prescription drug information in accordance with electronic prescribing standards published by the Secretary under section 1860D–4(e)(4) of the Act. We note that, depending on the circumstances, provisions in the existing physician self-referral regulations may provide sufficient protection for the donation of these items and services to physicians.

This proposed rule sets forth the terms and conditions of the MMA-mandated physician self-referral exception for certain arrangements involving the donation of electronic prescribing technology. The MMA-mandated anti-kickback statute safe harbor is being implemented in a separate rulemaking by the Office of Inspector General (OIG). We have attempted to ensure as much consistency as possible between our proposed electronic prescribing exception and the corresponding safe harbor proposed by OIG, given the differences in the respective underlying statutes. We intend the final rules to be similarly consistent.

Section 1877(b)(4) of the Act authorizes the Secretary to create regulatory exceptions for financial relationships that he determines do not pose a risk of program or patient abuse. Using this authority, this proposed rule also sets forth terms and conditions for two separate physician self-referral exceptions for certain arrangements involving the donation of electronic health records software and directly related training services. Information technology, and electronic health records in particular, supports treatment choices for consumers and enables

better and more cost-effective care, while maintaining the levels of security and privacy that consumers expect. We seek to encourage the adoption of such technology through this proposed rulemaking. We also intend to monitor the progress made toward fully interoperable electronic health records systems, as we believe that systems that are fully interoperable and certified can mitigate many of our concerns regarding the potential anti-competitive effects of stand-alone electronic health records systems.

II. Provisions of the Proposed Rule

As required by section 101 of the MMA, this proposed rule would add new paragraph (v) to § 411.357. New paragraph (v) would describe more specifically: (1) The items and services protected by the new electronic prescribing exception mandated under section 101 of the MMA; (2) the conditions under which offering these items and services to physicians would be protected; and (3) the DHS entities and referring physicians covered by the electronic prescribing exception.

In addition, using our separate legal authority under section 1877(b)(4) of the Act, we are proposing two separate exceptions at § 411.357(w) and § 411.357(x) for electronic health records software and training services that are not covered by the MMA-mandated exception. New paragraphs (w) and (x) would describe more specifically: (1) The items and services protected by the new electronic health records exceptions; (2) the individuals and entities that may provide the protected items and services; and (3) the conditions under which the provision of items and services to physicians would be protected.

The proposed exceptions at § 411.357(v), § 411.357(w), and § 411.357(x) would, if implemented, create independent grounds for protection under the physician self-referral prohibition. For the convenience of the public, we are providing the following chart that lays out schematically the overall structure and approach of these proposed regulations, details of which are provided below in Sections II.A. and B. of this proposed rule. Readers are cautioned that the exceptions contain additional conditions and information not summarized here.

¹ Revised § 424.22(d), relating to home health services, became effective on April 6, 2001 (see our **Federal Register** notice dated February 2, 2001 (66 FR 8771)). In addition, the effective date of the final sentence of § 411.354(d)(1) relating to the definition of "set in advances" was delayed several times. The sentence never went into effect and was deleted in the Phase II regulation, effective July 26, 2004.

	MMA-mandated electronic prescribing exception	Pre-interoperability electronic health records exception	Post-interoperability electronic health records exception
Authority for Proposed Exception ..	Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.	Section 1877(b)(4) of the Social Security Act.	Section 1877(b)(4) of the Social Security Act.
Covered Technology	<i>Proposed:</i> <ul style="list-style-type: none"> • Items and services that are necessary and used solely to transmit and receive electronic prescription drug information. • Includes hardware, software, internet connectivity, and training and support services. 	<i>Proposed:</i> <ul style="list-style-type: none"> • Software used solely for the transmission, receipt or maintenance of electronic health records. • Directly-related training services. • Software <i>must</i> include an electronic prescribing component. 	<i>Proposed:</i> <ul style="list-style-type: none"> • <i>Certified</i> electronic health records software • Directly-related training services • Software <i>must</i> include an electronic prescribing component • Could include billing and scheduling software, provided that the core function of the software is electronic health records.
Standards With Which Donated Technology Must Comply	<i>Proposed:</i> <ul style="list-style-type: none"> • Foundation standards for electronic prescribing as adopted by the Secretary. 	<i>Proposed:</i> <ul style="list-style-type: none"> • Electronic prescribing component must comply with foundation standards for electronic prescribing as adopted by the Secretary. 	<i>Proposed:</i> <ul style="list-style-type: none"> • Product certification criteria adopted by the Secretary. • Electronic prescribing component must comply with foundation standards for electronic prescribing as adopted by the Secretary, to the extent these standards are not fully incorporated into the product certification criteria.
Permissible Donors	<i>Proposed:</i> <ul style="list-style-type: none"> • As required by statute, hospitals (to members of their medical staffs), group practices (to physician members), PDP sponsors and MA organizations (to Physicians). 	<i>Proposed:</i> <ul style="list-style-type: none"> • Hospitals to members of their medical staffs. • Group practices to physician members. • PDP sponsors. • MA organizations. 	<i>Proposed:</i> <ul style="list-style-type: none"> • Hospitals to members of their medical staffs. • Group practices to physician members. • PDP sponsors. • MA organizations.
Selection of Recipients	<i>Proposed:</i> <ul style="list-style-type: none"> • Donors may not take into account the volume or value of referrals from the recipient or other business between the parties. 	<i>Proposed:</i> <ul style="list-style-type: none"> • Donors may not take into account the volume or value of referrals from the recipient or other business between the parties. 	<i>Proposed:</i> <ul style="list-style-type: none"> • Donors may use criteria to select recipients that are not directly related to the volume or value of referrals or other business generated between the parties.
Value of Protected Technology	<i>Proposed:</i> <ul style="list-style-type: none"> • No specific dollar amount proposed for a cap on the value of protected technology. 	<i>Proposed:</i> <ul style="list-style-type: none"> • No specific dollar amount proposed for a cap on the value of protected items and services. 	<i>Proposed:</i> <ul style="list-style-type: none"> • No specific dollar amount proposed for a cap on the value of protected items and services. • May be greater than the cap on preinteroperability donations.

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

[If you choose to comment on issues in this section, please include the caption "Electronic Prescribing Exception: § 411.357(v)" at the beginning of your comment.]

The Congress, in mandating the creation of an electronic prescribing exception under the physician self-referral law, recognized the value of electronic prescription programs as a vehicle to reduce medical errors and to improve efficiencies in the health care system. (H.R. Conf. Rep. No. 108–391, at 456 (2003).) We believe that promoting the rapid adoption of electronic prescribing for Medicare Part D is beneficial to both health care providers and patients, and we have interpreted the mandate accordingly.

1. Protected Non-Monetary Remuneration

Section 1860D–4(e)(6) of the Act authorizes the creation of an exception only for the provision of items and services that are "necessary and used solely" to transmit and receive electronic prescription drug information. This proposed rule would clarify the items and services that would qualify for the new exception ("qualifying electronic prescribing technology").

a. "Necessary" Non-Monetary Remuneration

First, consistent with the MMA mandate, the proposed exception would protect only items or services that are "necessary" to conduct electronic prescription drug transactions. This might include, for example, hardware, software, broadband or wireless internet

connectivity, training, information technology support services, and other items and services used in connection with the transmission or receipt of electronic prescribing information. The exception would not protect arrangements in which DHS entities provide items or services that are technically or functionally equivalent to items that the receiving physician already possesses or services that the physician has already obtained. For example, we believe the exception would allow a hospital to provide a physician with a hand-held device capable of transmitting electronic prescribing information, even though the physician may already have a desktop computer that could also be used to send the same information. By contrast, 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 new software. We do not interpret the term “necessary” to preclude upgrades of equipment or software that significantly enhance the functionality of the item or service.

We believe that restricting the exception to “necessary” items and services is important to minimize the potential for abuse. However, we recognize that the donors of the items and services will not necessarily know which items and services the physician already possesses or has obtained. Accordingly, § 411.357(v)(7)(iv) would require the physician to certify that the items and services provided are not technically or functionally equivalent to those that the physician already possesses or has already obtained. The physician must update the certification prior to the furnishing of any necessary upgrades or items and services not reflected in the original certification. We are concerned that the certification process would be ineffective as a safeguard against fraud and abuse if it is a mere formality or if physicians simply execute a form certification provided by the DHS entity. The certification must be truthful, and we are proposing at § 411.357(v)(8) that the DHS entity must not have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the physician possessed or had obtained items and services that were technically or functionally equivalent to those donated by the entity. We are soliciting comments about other ways to address this concern.

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

b. “Used Solely”

In addition to the “necessary” standard, section 1860D–4(e)(6) of the Act provides that the items and services must be “used solely” for the transmission or receipt of electronic prescribing information. We believe that the Congress included this requirement to safeguard against abusive arrangements in which the remunerative technology might constitute a payment for referrals because it might have additional value attributable to uses other than electronic prescribing. Accordingly, the proposed exception at § 411.357(v) requires that the protected items and services be used solely to transmit or receive electronic prescribing information.

We are concerned that DHS entities might provide free or reduced cost software that bundles valuable general office management, billing, scheduling, or other software with the electronic prescribing features. Such additional remuneration would not meet the “used solely” requirement and would not be protected by the proposed electronic prescribing exception. However, the physician would not be precluded from purchasing from the DHS entity for fair market value additional technology not protected by the proposed exception.

We are mindful that hardware and connectivity services can be used for the receipt and transmission of a wide range of information services, including, but not limited to, electronic prescription information, and that many physicians may prefer to use a single, multi-functional device, especially a hand-held, rather than multiple single-use devices. Similarly, many physicians may prefer to use a single connectivity service. Accordingly, we are proposing to use our authority under section 1877(b)(4) of the Act to create an additional exception to protect the provision by DHS entities to physicians of hardware (including necessary operating system software) and connectivity services that are used for more than one function, so long as a substantial use of the item or service is to receive or transmit electronic prescription information. We propose to treat operating software as integral to the hardware and distinct from other software applications that are not necessary for the hardware to operate. Under this additional exception, protection would not extend to the provision of items or services that are only occasionally used for electronic prescribing. The additional exception would incorporate the definitions and conditions set forth in this proposed rulemaking and would also include conditions to address the additional risk of abuse posed by multi-functional items and services.

We are soliciting public comment about the standards that should appear in an additional exception for multi-functional hardware (including necessary operating system software) or connectivity services. In particular, we are soliciting public comment on methodologies for quantifying or ensuring that a substantial use of hardware and connectivity services is for the receipt or transmission of electronic prescribing information. We have considered how to quantify “substantial use” with respect to other provisions of the Act and its implementing regulations; here, we are specifically seeking comments regarding

an appropriate definition of “substantial use” in the context of electronic prescribing technology and its use. We are also soliciting public comment on the nature and amount of any cap that we should impose on the value of the donated multi-functional hardware or connectivity services.

2. Designated Health Services (DHS) Entities Protected by the Exception

In addition to describing the kinds of electronic prescribing technology that can be protected, section 1860D–4(e)(6) of the Act limits the kinds of entities that may provide this assistance, and the persons to whom assistance can be provided. Specifically, the statutory provision protects the donation of qualifying electronic prescribing technology when the donation is made by hospitals to members of their medical staffs, by group practices to their physician members, and by prescription drug plan (PDP) sponsors and Medicare advantage (MA) organizations to pharmacies, pharmacists, and physicians and other prescribing health care professionals.

The proposed regulation text largely mirrors the statutory language except where the statute refers to persons or entities other than physicians (that is, pharmacies, pharmacists, and non-physician prescribing health care professionals). We are proposing to limit the exception at § 411.357(v) to remuneration provided to physicians, because section 1877 of the Act is not implicated when remuneration is provided to non-physician prescribing health care professionals or to pharmacists and pharmacies that are not otherwise affiliated with a referring physician. To the extent that a hospital has a financial relationship with these parties, no exception is necessary. However, arrangements that do not implicate section 1877 of the Act can still violate the anti-kickback statute.

Proposed § 411.357(v)(1)(i) would protect donations of qualifying electronic prescribing technology provided by a hospital to physicians on its medical staff. We intend to protect donations only to physicians who routinely furnish services at the hospital. We do not intend for this exception to protect remuneration used to induce physicians who already practice at other hospitals to join the medical staff of a different hospital. We are soliciting comments on this issue.

Proposed § 411.357(v)(1)(ii) would protect donations of qualifying electronic prescribing technology provided by a group practice to its physician members. For purposes of the new exception, we propose to apply the

existing regulatory definitions of the terms “group practice” and “member of a group practice” (see § 411.352 and § 411.351, respectively). Further, the inclusion of paragraph § 411.357(v)(1)(ii) does not imply that the provision of the items and services by a group to its members necessarily requires a new exception, because the in-office ancillary services exception or the employment exception would apply in most circumstances, where needed. We believe the Congress included these relationships in section 1860D–4(e)(6) of the Act simply to encourage group practices to adopt electronic prescribing technology. We are soliciting comments regarding whether and how a group practice may appropriately furnish qualifying electronic prescribing technology to a “physician in the group practice,” as defined at § 411.351.

Proposed § 411.357(v)(1)(iii) would protect donations of qualifying electronic prescribing technology provided by a PDP sponsor or MA organization to prescribing physicians. We note that, in certain circumstances, donations of qualifying electronic prescribing technology may qualify for protection under the existing exception at § 411.355(c). In addition, although section 1860D–4(e)(6) of the Act also applies to the provision of qualifying electronic prescribing technology by PDP sponsors and MA organizations to pharmacies, pharmacists, and non-physician prescribing health care professionals in the plans’ networks, these financial relationships do not implicate section 1877 of the Act.

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

3. Additional Limitations on the Provision of Electronic Prescribing Technology

a. Promoting Compatibility and Interoperability

Section 1860D–4(e)(6) of the Act is integral to the electronic prescribing program established by section 101 of the MMA. Section 1860D–4(e)(6) of the Act provides that, in order to qualify for the physician self-referral exception, the qualifying electronic prescription

technology must be used to receive and transmit electronic prescription information in accordance with standards to be established by the Secretary for Part D electronic prescription drug programs. Consistent with section 1860D–4(e)(6) of the Act, proposed § 411.357(v)(2) would require that the items and services be provided as part of, or be used to access, an electronic prescription drug program that complies with the standards established by the Secretary for these programs. We are soliciting comments on whether the exception should permit qualifying electronic prescribing technology to be used for the transmission of prescription information regarding items and services that are not drugs (for example, supplies or laboratory tests).

Interoperable systems have the technical capacity to transmit and receive information from other devices and applications in a secure and intelligible manner. We believe that interoperability can serve as an important safeguard against fraud and abuse, because a requirement that protected technology be fully interoperable would mitigate the risk that an entity could offer free or reduced price technology to a referring physician as a means of maintaining or increasing that physician’s referrals to the entity. With interoperable electronic prescribing technology, the physician would be free to transmit prescriptions to any appropriate pharmacy.

At this time, there are no regulatory standards to ensure that electronic prescription information products are interoperable with other products. However, we note that interoperability may be required in the future under final regulations regarding the standards for the Part D electronic prescription drug program. To the extent that either the hardware or software can be interoperable, we propose at § 411.357(v)(3) to prohibit donors or their agents from taking any actions to disable or limit that interoperability or otherwise impose barriers to compatibility. We believe this condition is necessary to limit the ability of a donor, such as a hospital, to use the provision of items or services to tie the physicians to the facility.

We are 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. (See generally 44 U.S.C. § 3601(6) (pertaining to the management and promotion of electronic government services).) We are

soliciting public comment about this approach, our definition of the term “interoperable,” alternative means of ensuring the maximum level of interoperability, and the types of software currently available for electronic prescribing.

b. Value of Protected Technology

We are considering whether to limit the aggregate fair market value of all items and services provided to a physician from a single donor. We believe a monetary limit is appropriate and reasonable to minimize the potential for fraud and abuse. We are soliciting public comment on the amount of a cap that would adequately protect the program against abuse, the methodology used to determine the cap (for example, fixed dollar amount, percentage of the value of the donated technology, or another methodology), whether the same cap would be adequate if there were protection for the donation of multi-functional hardware and connectivity services, whether the cap should be reduced over time, and whether the cap places a disadvantage on smaller entities that do not have the financial resources of larger chains or organizations.

We are also interested in comments on the retail and nonretail 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. We have received varying estimates of the costs of implementing electronic prescribing through the comment process for our E-Prescribing and the Prescription Drug Program proposed rule published on February 4, 2005 in the **Federal Register** (70 FR 6256). We also have explored the available literature on the costs of implementing electronic prescribing. (See section IV of this preamble.) We caution that the cost of implementing an electronic prescribing program will not correlate necessarily to the amount of any cap if one is established. Moreover, we do not expect that donors will wish necessarily to donate the total amount that the technology costs or, depending on the size of a cap, the total amount ultimately protected in the final rule. Although we are interested in obtaining detailed information about the costs of the full range of technology so as to be fully informed on this matter, we do not expect that the final regulations will protect all possible costs.

c. Other Conditions

We seek to minimize the potential for abuse and to ensure that the protected technology furthers the congressional

purpose of promoting electronic prescribing as a means of improving the quality of care for all patients. We believe that any protected items and services must, to the extent possible, be usable by physicians for electronic prescribing for all patients to ensure that uninsured and non-Medicare patients receive the same benefits that the technology may engender, including reduction of errors and improvements in care. Some donated technology (such as software for tracking prescriptions or formularies of a particular MA organization's patients) may not be applicable to all patients. However, other technology (for example, hand-held devices and software that transmit prescriptions to pharmacies) is potentially usable for all patients, and physicians should not be restricted from using such technology for all patients. Accordingly, proposed § 411.357(v)(4) would require that, where possible, physicians must be able to use the protected technology for all patients without regard to payor status.

Proposed § 411.357(v)(5) would provide that neither the physician nor the physician's practice (including employees and staff members) may make the donation of qualifying electronic prescribing technology items or services a condition of doing business with the entity.

Proposed § 411.357(v)(6) and (v)(7) would incorporate conditions that are consistent with the conditions in the other regulatory exceptions under the physician self-referral prohibition. Paragraph (v)(6) would provide that the eligibility of a physician to receive items and services from a DHS entity, and the amount and nature of the items and services received, may not be determined in a manner that takes into account the volume or value of the physician's referrals to the DHS entity or other business generated between the physician and the DHS entity. This does not preclude selection criteria that are based upon the total number of prescriptions written by a physician, but the proposed regulation would prohibit criteria based upon the volume or value of prescriptions written by the physician that are dispensed or paid by the donor, as well as any criteria based on any other business generated between the parties. We are interested in comments with respect to other potential criteria for selecting medical staff recipients of donated technology. Also, the exception would not protect arrangements that seek to induce a physician to change loyalties from other providers or plans to the donor (for example, a hospital using an electronic prescribing technology arrangement to

induce a physician who is on the medical staff of another hospital to join the donor hospital's medical staff for a purpose of referring patients to the donor hospital). Proposed § 411.357(v)(7) would require the arrangement to be in writing, to be signed by the parties, to identify with specificity the items or services being provided and the value of those items and services, and to include the certification described in section II.A.1 of this proposed rule. To permit effective oversight of protected arrangements, the written agreement must cover all of the qualifying electronic prescribing technology to be furnished to the physician by the DHS entity. For example, if a hospital provides a piece of hardware under one arrangement and then subsequently provides a software program, the agreement regarding the software would have to include a description of the previously donated hardware (including its nature and value). In addition, the written agreement must include a certification by the physician that the items and services are not technically or functionally equivalent to any items or services that he or she already possesses or has already obtained.

Proposed § 411.357(v)(8) would provide that the DHS entity must not have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the physician possessed or had obtained items and services that were technically or functionally equivalent to those donated by the entity. In other words, the DHS entity would not be subject to sanctions under section 1877(g) of the Act if it did not know or have reason to suspect that the physician certification required under § 411.357(v)(7)(iv) was false.

B. Exceptions for Certain Arrangements Involving Electronic Health Records Items and Services: § 411.357(w) and § 411.357(x)

The implementation of electronic health information technology is a compelling national priority to improve our healthcare system. Interoperable electronic health information technology would allow patient information to be portable and to move with consumers from one point of care to another. This would require an infrastructure that can help clinicians gain access to critical health information when treatment decisions are being made, while keeping that information confidential and secure. We believe that the promise of a secure and seamless information exchange that reduces medical errors, improves the quality of patient care, and improves efficiency

will be realized only when we have a standardized system that is open, adaptable, interoperable, and predictable.

We believe that interoperable electronic health records technology, once implemented, has the potential to increase health care quality and improve efficiency, which are outcomes consistent with our goals in exploring Pay-for-Performance options. We believe it is important to promote these open, interconnected, interoperable electronic health records systems that help improve the quality of patient care and efficiency in the delivery of health care to patients, without protecting arrangements that hinder marketplace competition, serve as marketing platforms, or are mechanisms to influence inappropriately clinical decision-making.

Accordingly, in addition to the electronic prescribing exception, we are proposing to use our legal authority under section 1877(b)(4) of the Act to promulgate two new exceptions, at § 411.357(w) and § 411.357(x), to protect non-abusive arrangements involving the provision of software and directly related training services that are necessary and used to receive, transmit, and maintain the electronic health records of the entity's or physician's patients. The first exception would apply to donations made before the Secretary's adoption of product certification criteria, including criteria for the interoperability, functionality, and privacy and security of electronic health records technology (these criteria are referred to herein as "product certification criteria"), and would provide limited protection. For purposes of this rulemaking, we will refer to this exception as the "pre-interoperability" exception. The second exception would apply to donations made after product certification criteria are adopted by the Secretary. For purposes of this rulemaking, we will refer to this exception as the "post-interoperability" exception. In recognition of the reduction in the risk of fraud and abuse that may result from interoperable systems, the post-interoperability exception would offer broader protection than the pre-interoperability exception.

We are concerned about the risk of program abuse that may be posed by a DHS entity's provision of valuable technology to physicians. We believe that this risk increases as the value of the technology to the physician increases. The provision of electronic health records technology to physicians poses greater risk of abuse than the provision of limited electronic

prescribing technology, because electronic health records technology is inherently more valuable to physicians in terms of actual cost, avoided overhead, and administrative expenses of an office practice. However, in light of the potential patient benefits of electronic health records, we have attempted to construct exceptions that include several criteria designed to ensure that the exceptions do not pose a risk of program or patient abuse. We will continue to evaluate the risks posed by the donation to physicians of electronic health records technology and may refine or add additional safeguards to the final rule to ensure that the exceptions do not pose a risk of program or patient abuse. We are requesting comments on whether hardware, connectivity and related items and services should also be protected under either or both these exceptions, and, if so, under what conditions.

1. Pre-Interoperability Exception

[If you choose to comment on issues in this section, please include the caption "Pre-Interoperability Electronic Health Records Exception: § 411.357(w)" at the beginning of your comment.]

We wish to recognize the innovative early adopters of electronic health records technology and establish an exception to protect donations of such technology made before the Secretary has adopted product certification criteria for electronic health records. However, as noted above in section II.A.3 with respect to electronic prescribing, it is important that protected electronic health records software be interoperable to the extent technologically feasible and that neither donors nor their agents take any actions to disable or limit interoperability or otherwise impose barriers to compatibility. Unlike electronic prescribing, at this time, 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. Nonetheless, while product certification criteria are being developed, we are proposing the narrow pre-interoperability exception described below to protect certain donations of electronic health records technology in an effort to stimulate and promote the expansion of technology in the health care industry.

a. Covered Technology

We are proposing to protect only electronic health records software, that is, software that is essential to and used solely for the transmission, receipt, or

maintenance of patients' electronic health records. To be protected by this exception, the donated electronic health records software must have an electronic prescribing component. The required electronic prescribing component must consist of software that is used to receive and transmit electronically prescription drug information in accordance with electronic prescribing standards published by the Secretary under section 1860D-4(e)(4) of the Act. We are soliciting comments on whether the exception should permit the electronic prescribing component of electronic health record software to be used for the transmission of prescription information regarding items and services that are not drugs (for example, supplies or laboratory tests). Additionally, we are soliciting comments with respect to whether we should also or instead require that electronic health records software include a computerized provider order entry (CPOE) component. We are proposing at § 411.357(w)(8) not to protect the provision of other types of technology, including, for example, hardware, connectivity services, billing or scheduling software, or software that might be used by a physician to conduct personal business or business unrelated to the physician's medical practice. Although the proposed exception would protect necessary training services in connection with the software, the exception would not protect the provision of staff to physicians or their offices.

We are mindful that there may be particular constituencies, such as rural area providers, that lack sufficient hardware or connectivity services to implement effective electronic health records systems. We are soliciting comments addressing these special circumstances.

In order to protect further against abuse, we are considering including in the final regulations a definition of "electronic health records" for purposes of the exception. We are soliciting comments on how we should draft this definition. In particular, we are interested in public comments that address the types of software that should be protected; the retail and nonretail cost of this software; the ways in which this software is currently marketed (for example, individual applications versus bundled software packages); methods for defining the scope of protected software; and safeguards that might be imposed (either in the definition or separately) to ensure that the exception does not pose a risk of program or patient abuse. Finally, we are soliciting public comment on

whether and, if so, how to protect the provision of other kinds of electronic health information technology.

We are proposing to interpret "necessary" in the new exception consistent with our interpretation of the term in section II.A.1 of this proposed rule and to include a comparable provision at § 411.357(w)(5)(iv) to ensure that the exception does not protect the provision of items or services that are technically and functionally equivalent to items and services the physician currently possesses or has obtained. As with electronic prescribing technology, we are concerned that there may be a risk that physicians would intentionally divest themselves of functionally or technically equivalent technology that they already possess to shift costs to donors and we are soliciting public comment on whether and how to address this situation.

b. Standards With Which Donated Technology Must Comply

The pre-interoperability exception would require at § 411.357(w)(9) that any protected software must include an electronic prescribing component that complies with standards established by the Secretary for the Part D electronic prescription drug program. Moreover, as with the electronic prescribing exception discussed above, we would require at § 411.357(w)(2) that neither donor entities nor their agents take any actions to disable or limit interoperability of any component of the software or otherwise impose barriers to compatibility. We are also considering requiring protected software to comply with relevant Public Health Information Network preparedness standards, such as those related to BioSense. We are soliciting comments on these and other appropriate standards.

We are interested in comments addressing whether this pre-interoperability exception may have the unintended effect of impeding the beneficial spread of interoperable electronic health records systems by promoting closed or isolated systems or systems that effectively tie physicians to particular providers or suppliers. For example, a hospital that donates expensive technology to a physician may exercise control over that physician sufficient to preclude or discourage other systems or health plans from having access to the physician for their own networks.

c. Permissible Donors

Proposed § 411.357(w) would protect the same categories of donors and physicians as the proposed exception

for electronic prescribing items and services at § 411.357(v). We believe that donors should be limited to hospitals, group practices, PDP sponsors, and MA organizations because they have a direct and primary patient care relationship and therefore have a central role in the health care delivery infrastructure that justifies protection for the furnishing of electronic health records technology that would not be appropriate for other types of providers and suppliers, including providers and suppliers of ancillary services. Moreover, hospitals, group practices, PDP sponsors, and MA organizations are potentially in a better position to promote widespread use of electronic health records technology that has the greatest degree of openness and interoperability. We do not believe that providers and suppliers of ancillary services, such as laboratories, are well-positioned to advance the goal of widespread use of interoperable electronic health records for patients, nor would they have the same interest in doing so. Nevertheless, we are interested in comments regarding whether other categories of donors should be included and why. We are also interested in comments with respect to whether different or alternative conditions should apply to any category of donor. In addition, we note that some donations of electronic health records software and related training services may fit within existing exceptions, including those at § 411.352 (for group practices) and § 411.355(c) (for certain prepaid health plans).

d. Selection of Recipients

We are proposing at § 411.357(w)(4) a condition, consistent with other regulatory exceptions, that the eligibility of a recipient to receive items and services from a donor, and the amount and nature of the items and services received, may not be determined in a manner that takes into account the volume or value of the recipient's referrals to the donor or other business generated between the parties. We are interested in comments with respect to potential criteria for selecting physician recipients of donated electronic health records software and related training services.

e. Value of Protected Technology

We believe it would be appropriate to limit the aggregate value of the protected software and directly related training services that a DHS entity could provide to a physician under the exception. The cap under the proposed pre-interoperability exception would be directly related to any cap adopted in connection with the electronic

prescribing exception discussed in section II.A.3. of this proposed rule. We believe this approach is consistent with the purpose of the physician self-referral prohibition and would also minimize any competitive disadvantage for smaller entities that do not have the financial resources or potential volume of technology business of larger chains or organizations.

We are interested in comments regarding the appropriate amount and methodology of a limiting cap. In addition to an aggregate dollar cap, we are considering two alternative approaches: (1) A cap that would be set at a percentage of the value of the donated technology to the physician (thus requiring the physician to share the costs); or (2) a cap set at the lower of a fixed dollar amount or a percentage of the value of the technology to the physician. We are soliciting public comment about this approach, including comments on how a cap under this exception would relate to a cap under the exception proposed at § 411.357(v) and how the value of technology provided under the final exceptions would be aggregated. We are concerned that DHS entities may abuse the proposed exceptions for electronic prescribing items and services and electronic health records software and training services by selectively relying on both exceptions to maximize the value of technology provided to physicians as a means of disguising payments for referrals. We believe conditions should be included in the final regulation to prevent this abuse and are considering requiring an overall cap on value, as well as documentation requirements that integrate all technology provided under the final exceptions. We are interested in public comments that address the retail and nonretail costs (that is, the costs of purchasing from manufacturers, distributors, or other nonretail sources) of obtaining electronic health records software and training services necessary to promote the widespread adoption of electronic health records. We are also interested in comments that address the degree to which physicians may already possess items or services that could be used for electronic health records. In addition, we are soliciting comments on whether and, if so, how to take into account physician access to any software that is publicly available either free or at a reduced price.

f. Other Conditions

To ensure further that this new exception does not pose a risk of program or patient abuse and for the reasons discussed in section II.A.3 of

this proposed rule, we are incorporating in § 411.357(w) certain other conditions described above in connection with § 11.357(v). These include a restriction at § 411.357(w)(3) on conditioning business on the receipt of electronic health records technology, a restriction at § 411.357(w)(4) on the provision of items and services related to the volume or value of referrals, a documentation requirement at § 411.357(w)(5), and an all-payors requirement at § 411.357(w)(7). Proposed § 411.357(w)(10) would require that the arrangement not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission. Because the provision of valuable items and services to a referral source can be used to induce or reward referrals, compliance with the anti-kickback statute is required to ensure that the protected arrangements do not pose a risk of abuse. This condition is consistent with the other regulatory exceptions to the physician self-referral law and was discussed in the interim final rule published on March 26, 2004 in the **Federal Register** (69 FR 16108). We believe that requiring compliance with the anti-kickback statute is particularly important because of the high dollar value of electronic health records technology.

g. Sunset Provision

We are also proposing a provision at § 411.357(w)(11) that would sunset the pre-interoperability exception applicable to electronic health records software and training services at the time that the post-interoperability exception at § 411.357(x) (see discussion in section II.B.2 of this proposed rule) becomes effective.

2. Post-Interoperability Electronic Health Records Exception

[If you choose to comment on issues in this section, please include the caption "Post-Interoperability Electronic Health Records Exception: § 411.357(x)" at the beginning of your comment.]

We realize that variable (that is, non-standardized) adoption of electronic health records systems could discourage market forces and competition from improving healthcare. Interoperability could mitigate many of our concerns regarding the potential anti-competitive effects of stand-alone electronic health records. We recognize that stand-alone electronic health records systems, even if widely adopted, may not deliver the error reductions, cost savings or marketplace changes necessary to meet the Secretary's goals, and could even shift the market toward more

fragmentation. We believe that only open, interconnected, interoperable electronic health records systems will allow for the free flow of information necessary to realize the full potential benefits of this technology.

We anticipate that a process to identify product certification criteria, including uniform industry standards for interoperability, functionality, and privacy and security, may be completed in the next year. The health information technology contractors and the American Health Information Community (AHIC) will be considering processes to set standards and to certify and inspect electronic health records technology; these processes and standards will be recommended to the Secretary for recognition and adoption. A certified product will meet all of the criteria adopted by the Secretary, including criteria for interoperability, functionality, and privacy and security, through the process recognized by the Secretary. The post-interoperability exception will protect only the donation of certified electronic health records technology. We are soliciting comments on how these processes under development might impact the scope of a final exception for electronic health records.

Once the Secretary adopts product certification criteria for interoperable electronic health records technology, we intend to finalize the exception described below, which offers broader protection specific to the donation of certified electronic health records systems. We discuss below an expanded exception for the donation of electronic health records software that is certified in accordance with the product certification criteria and process adopted by the Secretary.

a. Covered Technology

We are proposing to expand the scope of covered software, potentially including other kinds of software, provided that the core functions of the donated software are electronic prescribing and electronic health records. It is our intent that electronic prescribing and electronic health records be the core functions of the protected donated technology, but we also want to ensure that integrated packages that could positively impact patient care are not excluded from the post-interoperability exception. We intend to protect systems that improve patient care rather than systems comprised solely or primarily of technology that is incidental to the core functions of electronic prescribing and electronic health records. Although the proposed exception would protect

necessary training services in connection with the software, we specify at § 411.357(x)(8) that the exception would not protect the provision of staff to physicians or their offices or the provision of items or services used by a physician solely to conduct personal business or business unrelated to the physician's medical practice. We are soliciting public comments on what types of software should be protected under the post-interoperability exception and methods for ensuring that electronic prescribing and electronic health records are the core functions of the donated technology. As with the pre-interoperability exception, we propose at § 411.357(x)(9) that the technology protected under this exception must include an electronic prescribing component, and we are soliciting comments with respect to whether we should also or instead require that electronic health records software include a CPOE component.

b. Standards With Which Donated Technology Must Comply

We are proposing in § 411.357(x)(2) that the donated electronic health records software must be certified in accordance with the product certification criteria adopted by the Secretary. In addition, we propose at § 411.357(x)(9) that the electronic prescribing component must comply with electronic prescribing standards established by the Secretary under the Part D program, to the extent those standards are not incorporated into the product certification criteria adopted by the Secretary. Accordingly, no protection would be available under the post-interoperability exception until product certification criteria are adopted.

c. Permissible Donors

In new § 411.357(x)(1), we are proposing to protect the same categories of donors protected under the pre-interoperability exception as discussed in section II.B.1 of this proposed rule. We are also considering whether to protect additional categories of donors and whether different or alternative conditions should apply to any category of permissible donor. We are interested in comments addressing the types of individuals and entities that should be protected, the degree of need for protection, and the safeguards that should be imposed to protect against fraud and abuse.

d. Selection of Recipients

Because certified, interoperable systems would offer enhanced

protection against some types of fraud and abuse, we are proposing to permit donors to use selective criteria for choosing recipients, provided that neither the eligibility of a recipient, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of the referrals or other business generated between the parties. Proposed § 411.357(x)(4) would enumerate several selection criteria that would be deemed not to be directly related to volume or value of referrals or other business generated between the parties. For example, selection criteria that are based upon the total number of prescriptions written by a physician would not be precluded, but the proposed regulation would prohibit criteria based upon the number or value of prescriptions written by the physician and dispensed or paid by the DHS entity, as well as criteria based on any other business generated between the parties. Also, the exception would not protect arrangements that seek to induce a physician to change loyalties from other providers or plans to the DHS entity.

We expect that this approach will ensure that donated technology can be targeted at physicians who use it the most, in order to promote a public policy favoring adoption of the technology, while discouraging problematic direct correlations with Medicare referrals (for example, a hospital offering a physician 10 new computers for every 500 referrals of Medicare payable procedures). We caution, however, that outside of the context of electronic health records, as specifically addressed in this proposed rule, and except as permitted in § 411.352(i) (special rules for productivity bonuses and profit shares distributed to group practice physicians), both direct and indirect correlations between the provision of goods or services and the volume or value of referrals or other business generated between the parties are prohibited. We are interested in public comments about this approach, including whether there may be unintended consequences that would inhibit the adoption of interoperable technology or lead to abusive arrangements and, if so, whether more or less restrictive conditions would be preferable. We are also soliciting public comments on other possible criteria that would be an acceptable basis for selecting recipients of the donated technology.

e. Value of Protected Technology

We are considering whether a larger cap on the value of the donated software would be appropriate. In the discussion of the pre-interoperability exception at section II.B.1 of this preamble, we noted various alternatives we are considering in connection with a limiting cap and outlined issues about which we are soliciting comments. We are considering similar issues, and are interested in similar comments, in connection with the appropriate amount of a cap for interoperable, certified technology donated under the post-interoperability exception.

We are interested in comments regarding the appropriate amount and methodology of a limiting cap. In addition to an aggregate dollar cap, we are considering two alternative approaches: (1) A cap that would be set at a percentage of the value of the donated technology to the physician (thus requiring the physician to share the costs); or (2) a cap set at the lower of a fixed dollar amount or a percentage of the value of the technology to the physician. We are soliciting public comment about this approach, including comments on how a cap under this exception would relate to a cap under the exceptions proposed at § 411.357(v) and § 411.357(w) and how the value of technology provided under the final exceptions would be aggregated. We are interested in public comments that address the retail and nonretail costs (that is, the costs of purchasing from manufacturers, distributors, or other nonretail sources) of obtaining electronic health records software and training services necessary to promote the widespread adoption of certified electronic health records systems. We are also interested in comments that address the degree to which physicians may already possess items or services that could be used for electronic health records. In addition, we are soliciting comments on whether and, if so, how to take into account physicians' access to any software that is publicly available either free or at a reduced price.

f. Other Conditions

Similar to the proposed electronic prescribing and pre-interoperability exceptions, the proposed post-interoperability exception would incorporate additional conditions as discussed in section II.A.3 above. These include a restriction at § 411.357(x)(3) on conditioning business on the receipt of electronic health records technology, a documentation requirement at § 411.357(x)(5), a requirement at § 411.357(x)(6) that the DHS entity not

have actual knowledge or act in reckless disregard or deliberate ignorance of the fact that the physician possesses or has obtained duplicative items or services, an all-payors requirement at § 411.357(x)(7), and a requirement at § 411.357(x)(10) that the arrangement not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission.

III. Collection of Information Requirements

[If you choose to comment on issues in this section, please include the caption "Collection of Information Requirements" at the beginning of your comment.]

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to evaluate fairly whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the exceptions that are being proposed by this document. The electronic prescribing exception and the electronic health records exceptions would include an information collection requirement; that is, there would be a written, signed agreement for the provision to a physician of qualifying electronic technology.

The exception at § 411.357(v) would apply to the donation of non-monetary remuneration (consisting of items and services in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information. The exceptions at § 411.357(w) and § 411.357(x) would apply to non-monetary remuneration consisting of items and services (in the form of electronic health records software and directly related training services) that is

necessary to receive, transmit, and maintain electronic health records.

These exceptions are limited to donations made by hospitals to physicians who are members of their medical staffs, by group practices to their physician members, and by PDP sponsors and MA organizations to physicians in their networks. Each of these arrangements must be in a writing that is signed by the parties and that identifies the items or services being provided and their value. In addition, the written arrangement must include a certification by the physician that the items and services to be provided are not technically or functionally equivalent to any items or services he or she already possesses or has already obtained.

The burden associated with the written agreement requirement is the time and effort necessary for documentation of the agreement between the parties, including signatures of the parties, and the signed certification by physicians.

We do not know how many hospitals, PDP sponsors, or MA organizations would use the exceptions that apply to qualifying electronic prescribing technology and electronic health records software and training services. However, as explained in section II.A.2 of this proposed rule, we expect that few group practices would use either exception because existing exceptions would likely apply to permit a group practice to provide its physician members with qualifying electronic prescribing items and services and electronic health records software and training services. Thus, few group practices would be affected by this exception and any related paperwork burdens.

In addition, because the donation of qualifying electronic prescribing technology and electronic health records software and training services is voluntary, we believe that some hospitals, PDP sponsors, and MA organizations will not avail themselves of this exception and will therefore not experience any paperwork burden.

Finally, we believe that, for those entities that choose to donate qualifying electronic prescribing technology or electronic health records software and training services to physicians, the paperwork burden will be limited by the terms of each exception. Each exception requires the donated items and services to be necessary and not duplicative of items and services the physician already possesses or has obtained.

We expect that every hospital, PDP sponsor, and MA organization that would choose to furnish qualifying

electronic prescribing technology or electronic health records software and training services to physicians would likely use a model agreement that lists or describes the electronic items and services to be donated. We expect that State or national organizations representing lawyers, physicians, group practices, hospitals, PDP sponsors, and MA organizations would create model agreements for their members. However, we also expect that attorneys for large providers (for example, academic medical centers) would create model agreements. We estimate that an entity that creates a model agreement would have to spend approximately 3 hours to draft two model agreements (one for each exception). We estimate that it would take a donor hospital 20 minutes to both tailor each model agreement for each physician and to sign each agreement. We estimate that each physician would also spend 20 minutes reading and signing each agreement and completing the necessary certification. We recognize that a physician and an entity would have to understand the differences between the items and services that an entity is offering and the items and services that the physician already possesses or has obtained.

As of April 2003, there were 586,411 physicians who provided Part B physician services to beneficiaries and (as of December 31, 2003) 6,057 hospitals that participated in Medicare. As of January 1, 2006, we expect that there would be at least two PDP sponsors serving each State and at least 270 MA plans. We assume that each physician is on the medical staff of two hospitals and would treat patients who are members of one PDP and two MA plans.

We do not believe that physicians would be willing now to participate in more than one type of electronic system because of the time necessary to learn to use each system efficiently. Because items and services must be necessary and used solely for electronic prescribing or electronic health records, we estimate that, on average, physicians would receive items and services from only one entity. (We recognize that two or more entities could each provide necessary items and services to a physician under an exception, but we do not expect that to occur in the near future.)

We are unable to estimate how many entities would provide these items or services to physicians annually. However, because the Federal government has established a goal of having most Americans' health information in electronic form by 2014, we estimate that one-ninth of all entities

would begin the process of developing or using electronic prescribing and electronic health records each year.

Taking all of this into account, we expect that no more than 150 State or national organizations or lawyers for large hospital systems, PDP sponsors, or MA organizations would draft agreements for the 6,057 hospitals, 100 PDP sponsors, and 270 MA organizations. Because we estimate it would take 3 hours to prepare a model agreement, there may be at least two model agreements, and that 150 organizations would each prepare these agreements, it could take a maximum of 900 hours to prepare all model agreements (2 types of model agreements \times 150 model agreements \times 3 hours to prepare = 900 hours).

To calculate the maximum number of hours that reasonably would be required to complete the agreements, we assume that 10 percent of the 586,411 physicians would sign an agreement for electronic items and services. Therefore, we estimate that annually the donating entities may spend 19,547 hours in completing and signing the agreements (20 minutes \times [.10 \times 586,411 physicians] = 19,547 hours). In addition, we estimate that the cumulative burden on physicians would also be 19,547 hours.

An additional burden associated with the requirements for both exceptions would be that of maintaining documentation, and, if necessary, making it available to the Secretary upon request. We believe that the information we are requiring entities to maintain is information that they would already maintain in the ordinary course of business. Thus, any information the Secretary would need would already have been collected and maintained by the entities. Moreover, making information available to the Secretary should rarely be necessary, as the information is not collected routinely by the Secretary. Rather, the information would likely be collected only during the conduct of an administrative action, investigation, or audit involving a Federal governmental agency regarding specific individuals or entities. The paperwork burden associated with these types of reviews is exempt from the PRA under 5 CFR 1320.4(a).

If you comment on these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn: Jim Wickliffe, CMS-1303-P, Room C4-26-05, 7500 Security

Boulevard, Baltimore, MD 21244-1850; and
Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: CMS Desk Officer, Fax (202) 395-6974.

IV. Regulatory Impact Statement

[If you choose to comment on issues in this section, please include the caption "Regulatory Impact Statement" at the beginning of your comment.]

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995, Pub. L. 104-4, the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibilities of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for final rules with economically significant effects (that is, a final rule that would have an annual effect on the economy of \$100 million or more in any one year, or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities). Because we believe that the economic impact of this proposed rule would not exceed \$100 million annually, we have not prepared an RIA. However, we have analyzed alternatives and assessed benefits and costs in order to provide a basis for informed decisions.

This proposed rule would create new exceptions to the physician self-referral prohibition to allow certain entities to provide technology-related items and services to physicians for purposes of conducting electronic prescribing and maintaining electronic health records. The exceptions would protect donations of qualifying electronic prescribing technology and electronic health records software and directly related

training services made by a hospital to a physician member of its medical staff, a group practice to a physician member, and a PDP sponsor or MA organization to a prescribing physician, provided that certain conditions are satisfied. The exceptions should facilitate the adoption of electronic prescribing and electronic health records technology by filling a gap rather than creating the primary means by which physicians will adopt these technologies. In other words, we do not believe that donor entities will fund all of the health information technology used by physicians.

The proposed rule on electronic prescribing standards, which was published on February 4, 2005 (70 FR 6256), takes into consideration the expected cost for the hardware, software, training and information technology needed by prescribing practitioners, including physicians. In the preamble to that rule, we presented a Regulatory Impact Analysis covering the expected effects of electronic prescribing and the specific standards proposed. Our analysis showed the possibility of substantial and economically significant positive health effects on consumers and net positive economic effects on affected entities, such as physicians, pharmacies, and health plans. Our analysis focused on the likelihood that PDP sponsors and MA organizations would find it in their interest to pay some or all of the costs of qualifying electronic prescribing technology or electronic health records software and training services to encourage physician adoption.

This proposed rule would remove a potential obstacle to the provision of qualifying electronic prescribing technology and electronic health records software and directly related training services (for purposes of this Regulatory Impact Statement, herein referred to as "qualifying health information technology") by certain entities. Although this proposed rule applies to donations of qualified health information technology donations by hospitals, group practices, PDP sponsors, and MA organizations, we expect that many donor entities may not need to use these proposed exceptions, given the existing exceptions at § 411.352 and § 411.355(c).

Of particular importance, managed care services furnished by prepaid health plans or their contractors may fall within a previously codified exception (see § 411.355(c)). We believe that prepaid plans have substantial economic incentives to encourage the adoption of health information technology by contracting physicians,

incentives that are larger than those for most other entities. We are interested in public comments on whether this existing exception is sufficiently broad to accommodate non-abusive arrangements and to foster the adoption of health information technology.

Regardless of whether donations would be allowed under existing exceptions or those that are included in this proposed rule, we encourage commenters to provide information on the costs that would likely be incurred by entities that would choose to furnish qualifying health information technology to physicians, as well as other related costs that would likely be incurred by both donors and physicians, such as costs incurred for changes in office procedures.

Our analysis under Executive Order 12866 of the expenditures that entities may choose to make under this proposed rule is restricted by potential effects of outside factors, such as technological progress and other market forces, future certification standards, and companion proposed anti-kickback statute safe harbors. Furthermore, both the costs and potential savings of electronic prescribing, electronic health records, computerized physician order entry, and billing and scheduling software vary to the extent to which each element operates as a stand-alone system or as part of an integrated system. We welcome comments that will help identify both the independent and synergistic effects of these variables.

As discussed in the February 4, 2005 E-Prescribing proposed rule at 70 FR 6268 through 6273, we expect that donors may experience net savings with electronic prescribing in place and patients would experience significant positive health effects. We have not repeated that analysis in this proposed rule.

There are numerous studies reporting that electronic health records in the ambulatory setting can result in a substantial improvement in clinical process. The effects of electronic health records include: (1) Reducing unnecessary or duplicative lab and radiology test ordering by 9 to 14 percent (Bates, D., *et al.*, "A randomized trial of a computer-based intervention to reduce utilization of redundant laboratory tests," *Am. J. Med.* 106(2), 144–50 (1999)); (Tierney, W., *et al.*, "The effect on test ordering of informing physicians of the charges for outpatient diagnostic tests," *N. Engl. J. Med.* 322(21): 1499–504 (1990)); (Tierney, W., *et al.*, "Computerized display of past test results. Effect on outpatient testing," *Ann. Intern. Med.* 107(4): 569–74 (1987)); (2) lowering ancillary test

charges by up to 8 percent (Tierney, W., *et al.*, "Computer predictions of abnormal test results. Effects on outpatient testing," *JAMA* 259: 1194–8 (1988)); (3) reducing hospital admissions due to adverse drug events (ADEs), costing an average of \$17,000 each, by 2 to 3 percent (Jha, A., *et al.*, "Identifying hospital admissions due to adverse drug events using a computer-based monitor," *Pharmacoepidemiology and Drug Safety* 10(2), 113–19 (2001)); and (4) reducing excess medication usage by 11 percent (Wang, S., *et al.*, "A cost-benefit analysis of electronic medical records in primary care," *Am. J. Med.* 114(5): 397–403 (2003)); (Teich, J., *et al.*, "Effects of computerized physician order entry on prescribing practices," *Arch. Intern. Med.* 160(18): 2741–7 (2000)). There is also evidence that electronic health records can reduce administrative inefficiency and paper handling. (Khoury, A., "Support of quality and business goals by an ambulatory automated medical record system in Kaiser Permanente of Ohio," *Eff. Clin. Pract.* 1(2): 73–82 (1998)). Most recently, a large study evaluating the impact of electronic health records on resource utilization in two States found that physician visits decreased by 9 percent 2 years after implementation.

These studies show a consistent pattern of clinical utilization reductions that have been reported to arise from electronic health records use in ambulatory settings. Although financial estimates were not performed in these studies, these utilization reductions could yield savings that accrue to Medicare because of its use of volume-based payments for ambulatory and inpatient care. Other studies have estimated that electronic health records in the ambulatory setting would save \$78 billion to \$112 billion annually, across all payors. This estimate includes up to \$34 billion in annual savings from ambulatory computerized provider order entry (Johnston, D., *et al.*, "The Value of Computerized Provider Order Entry in Ambulatory Settings," Center for IT Leadership, Wellesley, MA (2003)) and up to \$78 billion annually from interoperability of electronic health records (Walker, J., *et al.*, "The Value of Health Care Information Exchange and Interoperability," *Health Affairs*, <http://www.healthaffairs.org> (online exclusive) (2005)).

At the same time, the costs of electronic health records and other health information technology are very substantial. For example, one estimate of HIPAA compliance costs alone indicated that hospitals would need to spend \$14 billion and health plans more than \$5 billion. (Duncan, M., "August

2002 HIPAA Panel Results: Expected Costs/Benefits,” Gartner (2002)). The range of cost estimates for electronic health records alone is wide. At one extreme, there are software systems under development that may be offered to physician settings free or at the cost of perhaps several thousand dollars, while others may cost \$20,000 to \$30,000. Extrapolated to the universe of health plans, hospitals, and physicians, total investment costs are likely to reach the billions of dollars.

It is unclear how rapidly adoption is now occurring. A recent study indicates “practices are encountering greater-than-expected barriers to adopting an [electronic health records] system, but the adoption rate continues to rise.” (Gans, D., *et al.*, “Medical Groups’ Adoption of Electronic Health Records and Information Systems,” *Health Affairs*, September/October 2005). This study dealt only with group practices, and found greater difficulties in smaller groups. We can infer similar implementation difficulties for individual physician practices. For example, this study found the average initial cost of implementing an electronic health records system to be \$33,000 per physician, with maintenance costs of \$1,500 per physician per month, numbers which “would translate into about a 10 percent reduction in take-home pay each year for most primary care practices” if amortized over 5 years. (See Gans, D.). Another recent study reviews a broader range of providers and is equally pessimistic, arguing that the economic incentives of most stakeholders do not support health information technology investments. According to that article, “The greater marvel is that any physician, at his or her personal expense, would install a system that * * * saves money for every health care stakeholder except the adopting physician.” (Kleinke, J.D., “Dot-Gov: Market Failure and the Creation of a National Health Information Technology System,” *Health Affairs*, September/October 2005). This study is also more pessimistic than most about the business case for managed care plans to make health information technology investments, arguing that investments benefit not only the investing firm but also its competitors. Many other studies, discussed below, are more optimistic about economic returns to physicians. However, the disparate results illustrate the uncertainty that prevents us from making confident quantitative estimates of rates of adoption.

We assume that health information technology costs and benefits will be realized eventually. Even without

government intervention, there is a lively market today, and as consensus standards evolve, that market will grow. The question as to the regulatory impact of the proposed rule is: Taking into account available policy instruments (notably the development of interoperability standards), to what extent would the use of these proposed physician self-referral exceptions accelerate adoption of electronic prescribing and electronic health records?

We do not have good baseline information. There are numerous estimates for the adoption of electronic prescribing by health plans, hospitals, physicians, and (for prescribing of drugs only) pharmacies. However, these estimates are clouded by uncertainty. For example, some studies count facsimile transmission of prescriptions as electronic prescribing. The majority of physician offices now use computers, and have high-speed Internet access, but less than one in five uses electronic health records. (Goldsmith, J., *et al.*, “Federal Health Information Policy: A Case of Arrested Development,” *Health Affairs*, July/August 2003 (citing 17 percent adoption)). The Gans study found that about 12 percent of medical group practices have a fully implemented electronic health records system, and another 13 percent are in the process of implementation. For smaller group practices these percentages fall to 10 and 10, respectively. (See Gans, D., *supra*).

As discussed below, we estimate that 2 percent of physicians and 2 percent of all hospitals, group practices, MA organizations and PDP sponsors would be affected by these proposed exceptions each year. That is, only one in five of the potential donors of qualifying health information technology will utilize these exceptions. As explained in the February 4, 2005 E-Prescribing proposed rule (70 FR 6256), we believe that between 5 and 18 percent of prescribers, including physicians, are currently participating in some electronic prescribing. In addition, we explained that we believe that the proportion of prescribers using electronic prescribing would increase by about 10 percent annually over the next 5 years (70 FR 6256). We believe it is likely that about one in five of those prescribers would receive assistance under these proposed exceptions and another one in five would receive assistance under the exceptions already in place that apply to managed care plans and group practices.

These estimates depend primarily on the decisions of MA organizations and PDP sponsors as to whether to provide

assistance to physicians for electronic prescribing and electronic health records and the decisions of group practices to implement these systems. We welcome information about the intentions of MA organizations and PDP sponsors to make donations of qualifying health information technology to physicians and the willingness of group practices to implement these systems.

Even if we were able to determine more precisely the number of physicians who are currently engaged in, and the number of physicians who will engage in, electronic prescribing, we cannot estimate with certainty the number of those physicians who would receive donated items and services. Some entities may be unwilling or unable to donate items or services, and some physicians already have the requisite items and services. In addition, we cannot estimate with certainty the cost of the qualifying health information technology that a physician would need from a donor. Part of this uncertainty is due to varying needs for the technology. For example, we expect that for face-to-face encounters with patients in hospital inpatient and outpatient departments, physicians would primarily use a hand-held device, for example, a personal digital assistant (PDA). Alternatively, physicians might find it easier to use one of the hospital's computers that increasingly are becoming located near patient rooms and throughout outpatient departments.

Although we do not know the cost of the electronic prescribing technology or of the electronic health records software that ultimately may be donated under these proposed exceptions, we describe below several studies of the costs and benefits of equipping doctors with such technology and software. The speed of adoption will depend on the extent to which prescribers realize net benefits (discussed extensively in our proposed rule on E-Prescribing) and on the extent to which our proposed exceptions (when made final) incrementally affect the costs and savings of the technology.

One study of data on the costs associated with an internally developed electronic medical record system for several internal medicine clinics at an integrated delivery system indicated that software development and maintenance would cost about \$1,600 per provider per year. (See Wang, *supra*.) Use of commercially available software may cost twice as much. Financial benefits of electronic health records include not having to “pull” patient charts whenever a patient is to be seen and reduced transcription costs. In addition, electronic clinical decision

support has been shown to reduce ADEs and redundant radiology and clinical laboratory tests, and up-to-date information about alternative drugs reduces the use of expensive medications. Finally, when a medical record has complete and accurate information about services provided, billing errors are reduced, including failure to bill for a furnished service. The 5-year cost-benefit analysis of the internally developed electronic medical records system discussed above indicated savings per practitioner. (See Wang, *supra*.)

In another article, Dr. Kenneth Adler reported on his 86-physician, multi-specialty group practice's adoption of an electronic health records system beginning in 2003. (Adler, K., "Why It's Time to Purchase an Electronic Health Record System," *American Academy of Family Practitioners*, November/December 2004.) This group practice found that its electronic health records system improved communication, access to data, and documentation, which led to better clinical and service quality. This electronic health records system also saved the group practice money, and Dr. Adler expects that other group practices that adopt electronic health records systems will save money in addition to the other benefits listed above.

In a third study, the Central Utah Multi-Specialty Clinic, a 59-physician, nine-location group practice installed an electronic medical records system in April 2002. (Barlow, S., *et al.*, "The Economic Effect of Implementing an EMR in an Outpatient Clinical Setting," *J. of Healthcare Information Management*, 18(1): 46–51 (2004).) During its first year of operation, the group practice experienced direct reductions in spending and increases in revenue of more than \$952,000 compared with the prior year, and anticipates savings of more than \$8.2 million over the first 5 years of implementation. Once again, the savings are expected to result from reduced transcription costs, a reduced number of paper charts and related maintenance (including storage), and more appropriate coding because of appropriate documentation. (This study did not include information about the start-up costs of the electronic medical record system or the annual continuing costs. Therefore, caution should be used in drawing conclusions on any cost savings based on the results of this study.)

Finally, we note that the Center for Information Technology Leadership (CITL), in its 2003 report, "The Value of Computerized Provider Order Entry in

Ambulatory Settings"² found that the average first year total cost of a basic electronic prescribing software system was approximately \$3,000 per physician. This estimate was based on a survey of commercially available software.

We believe that donations allowed by this proposed rule would create no net costs to the economy. This rule would permit cost-shifting, allowing hospitals, PDP sponsors, and MA organizations to bear financial burdens that otherwise would have been borne by physicians and their patients. We anticipate that electronic prescribing and electronic health records technology ultimately should save donor entities and physicians the costs and other burdens associated with incorrect drug prescribing or dispensing, and result in reductions in the costs of medical transcribing and other paperwork. Similarly, obtaining accurate health records on a timely basis should benefit patients, physicians, hospitals, MA organizations, and PDP sponsors. The February 4, 2005 proposed rule on E-Prescribing standards (70 FR 6256) cites an estimate from the CITL that nationwide adoption of electronic prescribing would eliminate nearly 2.1 million ADEs per year. In turn, this reduction of ADEs would prevent nearly 1.3 million provider visits, more than 190,000 hospitalizations, and more than 136,000 life-threatening ADEs (70 FR 6268). We hope to see a significant reduction in ADEs each year as nationwide adoption occurs.

We estimate that 10 percent of the 586,411 physicians who provide services to Medicare beneficiaries would adopt electronic prescribing technology and electronic health records software and software training each year. We believe it is likely that health plans or hospitals would donate software or other items or services to no more than 20 percent of these physicians (or to fewer than 12,000 physicians) under our proposed exceptions and perhaps another 20 percent of these physicians (again fewer than 12,000 physicians) would receive donations under the existing exceptions that apply to managed care services and to group practices. We estimate that, at most, each physician would receive a total of \$3,000 worth of donated items and services under the proposed exceptions. Therefore, assuming that 2 percent of physicians (one-fifth of all adopting physicians) would receive

\$3,000 worth of donated items and services in each of the two categories (electronic prescribing and electronic health records), annual donations approximate \$36 million.

We expect that many physicians already own hand-held devices and will have begun to computerize their own medical practices. We also expect that hospitals, MA organizations, and PDP sponsors would see immediate financial and patient care benefits from the expanded use of electronic prescribing and electronic health records. We are particularly interested in comments concerning our estimated costs to hospitals for donating these items and services and the expected savings from reductions in medical transcription, redundant diagnostic testing, ADEs, and readmissions to hospitals. We anticipate that these savings will be greater than the costs incurred by entities using these exceptions, but we cannot quantify the savings at this time.

We note that an unexpected benefit recently occurred. The Atlantic Information Service reported in AIS E-Health on September 15, 2005 that patients from the Veterans Administration (VA) Hospital in New Orleans had been evacuated to other VA hospitals throughout the United States because of the effects of Hurricane Katrina. (See (www.aishealth.com/EHealthBusiness/091505.html)). Because the VA system makes extensive use of electronic prescribing and electronic health records, complete patient medical information was quickly made available to VA clinicians throughout the country.

The estimates above are highly sensitive to assumptions. The permitted value of donated items and services under the proposed exceptions might be half as much or twice as much as discussed above. The rate of adoption might be higher or lower than estimated. The proportion of physicians receiving remuneration could be lower or higher than estimated, depending on the willingness of hospitals, group practices, MA organizations, and PDP sponsors to subsidize investment in health information technology. We welcome comments on these variables and independent estimates as to the likely rates of adoption and subsidization.

At this time, there are mixed signals about the potential of electronic prescribing and electronic health records to reduce costs. For example, many estimates are based in part on the reduction of medical errors. However, one study has also shown that medical errors, and potentially costs, can increase if software is poorly designed

² Center for Information Technology (CITL, a research organization chartered in 2002) <http://www.citl.org>, Wellesley, MA (781-416-9200) 2003 report: "The Value of Computerized Provider Order Entry in Ambulatory Care."

or implemented (Koppel, *et al.*, 2005). Therefore, achieving reliable cost savings requires a more substantial transformation of care delivery that goes beyond simple use of any one kind of health information technology.

This rule likely would have an effect on the actual rate of adoption of electronic prescribing and electronic health records technology. Potential donors may be unlikely to provide assistance unless they believe it would accelerate the adoption of the technology. To the extent adoption is advanced, the costs and benefits of these technologies will be realized sooner. However, we are unable to provide any quantitative estimate of the likely effect of these proposed exceptions, taken alone, in the larger panorama of all health information technology investment decisions, market evolution, standards adoption, and use of existing physician self-referral exceptions. We welcome comment on whether information exists that would allow such estimates, and what they might be.

Finally, we believe it unlikely that annual effects would exceed \$100 million in the 5-year timeframe that we generally use in our economic impact projections. If our estimate of the independent and direct effects of these new exceptions is accurate, and if the resulting acceleration in adoption is relatively small, this proposed rule would not be a major rule. However, we have completed all the elements of a Regulatory Impact Analysis because the uncertainty is so great.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess the anticipated costs and benefits of Federal mandates before issuing any rule that may result in the mandated expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars (a threshold adjusted annually for inflation and now approximately \$120 million). This proposed rule would impose no mandates. Any actions taken under this rule would be voluntary. Furthermore, such actions are likely to result in cost savings, not net expenditures, and any expenditures would be undertaken by government-owned hospitals in their business capacity, without any necessary impact on State, local, or tribal governments, or their expenditure budgets, as such.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or

otherwise has Federalism implications. For the reasons given above, this proposed rule, if finalized, would not have a substantial effect on State or local governments.

B. Impact on Small Businesses

The RFA requires agencies to analyze options for regulatory relief for small entities when a proposed rule may create a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and physicians are considered small entities, either by nonprofit status or by having revenues of less than \$6 million a year. Almost all physicians in private practice (or all the practices of which they are members) are small entities because their annual revenues do not meet the Small Business Administration's \$8.5 million threshold for small physician practices. Individuals and States are not included in the definition of a small entity, and this proposed rule would not have a financial impact on small governmental entities.

We have determined that this proposed rule would not have a significant impact on small entities because it does not increase regulatory burden or otherwise meet the RFA standard of "significant impact." While the aggregate impacts would be substantial, it is unlikely that near term effects on individual practitioners would be substantial as a proportion of revenues (for example, a \$3,000 remuneration compared to typical practice revenues in the hundreds of thousands of dollars). We expect our proposed new exceptions ultimately to be highly beneficial to physicians, hospitals, and pharmacies (most in each category are small entities), as well as to affected entities and persons who are not "small entities" as defined in the RFA—PDP sponsors, MA organizations, and our beneficiaries. We welcome comment on these conclusions.

Nothing in this proposed rule meets any of the other thresholds requiring in-depth analysis. Although it affects a substantial number of small rural hospitals, there is no significant economic effect on small rural hospitals (more than 3 to 5 percent of total costs/revenues), it imposes no unfunded mandates or costs on either private or public entities, and it neither preempts State law nor otherwise has Federalism implications.

C. Conclusion

We have concluded that this proposed rule would not have a significant

economic effect. Although the proposed exceptions may shift costs from physicians and patients to permissible donor entities and may lead to faster adoption of health information technology with substantial benefits, it is unclear whether, and we believe unlikely that, these effects would reach the threshold of \$100 million annually in the near term, even though the long-term cumulative costs and benefits are likely to be many times this threshold. This rule would remove a potential obstacle to certain entities providing qualifying electronic prescribing technology and electronic health records software and directly related training services to physicians. The rule would permit cost shifting, allowing hospitals, MA organizations and PDP sponsors to bear financial burdens that otherwise would have been borne by physicians and their patients. We believe that this rule will provide substantial positive health effects on consumers and net positive economic effects on affected entities, including physicians, hospitals, and MA organizations.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined that this rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 411

Kidney diseases, Medicare, Physician referral, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services would amend 42 CFR chapter IV as set forth below:

PART 411—[AMENDED]

1. The authority for part 411 is amended to read as follows:

Authority: Secs. 1102, 1871, and 1877(b)(4) and (5) of the Social Security Act (42 U.S.C. 1302, and 1395hh, and 1395nn(b)(4) and (5)).

Subpart J—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

2. Section 411.357 is amended by adding paragraphs (v), (w), and (x) to read as follows:

§ 411.357 Exceptions to the referral prohibition related to compensation exceptions.

* * * * *

(v) *Electronic prescribing items and services.* Non-monetary remuneration (consisting of items and services in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information, if all of the following conditions are met:

(1) The items and services are provided by a—

(i) Hospital to physicians who are members of its medical staff;

(ii) Group practice (as defined at § 411.352) to physicians who are members of the group practice (as defined at § 411.351); or

(iii) PDP sponsor or MA organization to prescribing physicians.

(2) 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.

(3) The entity (or any person on the entity's behalf) must 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.

(4) For items or services that are of the type that can be used for any patient without regard to payor status, the donor may not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

(5) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services a condition of doing business with the donor.

(6) 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.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items or services being provided and the value of those items and services;

(iii) Covers all of the electronic prescribing items or services to be furnished by the entity; and

(iv) Contains 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.

(8) The entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the fact that the physician possessed or had obtained items and services that were technically or functionally equivalent to those donated by the entity.

(w) *Electronic health records items and services that are not certified.* Non-monetary remuneration (consisting of items and services in the form of software or directly related training services) necessary and used solely to receive, transmit, and maintain electronic health records, if all of the following conditions are met:

(1) The items and services are provided by a—

(i) Hospital to physicians who are members of its medical staff;

(ii) Group practice (as defined at § 411.352) to physicians who are members of the group practice (as defined at § 411.351); or

(iii) PDP sponsor or MA organization to prescribing physicians.

(2) The entity (or any person on the entity's behalf) must not take any actions to limit or restrict unnecessarily the use or compatibility of the items or services with other electronic health records items or services or electronic health information systems.

(3) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, nor the amount or nature of the items or services, a condition of doing business with the donor.

(4) Neither the eligibility of a physician, 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.

(5) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items or services being provided and the value of those items and services;

(iii) Covers all of the electronic health records items and services to be furnished by the entity to the physician; and

(iv) Contains 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.

(6) The entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the fact that the physician possessed or had obtained items and

services that were technically or functionally equivalent to those donated by the donor.

(7) For items or services that are of the type that can be used for any patient without regard to payor status, the donor may not restrict or take any action to limit the physician's right or ability to use the items or services for any patient.

(8) The items and services do not include any billing, scheduling, or other similar general office management or administration software or services, nor do the services include staffing of physician offices.

(9) The electronic health records technology contains electronic prescribing capability that complies with the electronic prescription drug program standards under Medicare Part D at the time the items and services are furnished.

(10) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission.

(11) The donation was made before the effective date of paragraph (x) of this section.

(x) *Certified electronic health records items and services.* Non-monetary remuneration (consisting of items and services in the form of software or directly related training services) necessary to receive, transmit, and maintain electronic health records, if all of the following conditions are met:

(1) The items and services are provided by a—

(i) Hospital to physicians who are members of its medical staff;

(ii) Group practice (as defined at § 411.352) to physicians who are members of the group practice (as defined at § 411.351); or

(iii) PDP sponsor or MA organization to prescribing physicians.

(2) The technology is certified in accordance with criteria adopted by the Secretary that are in effect at the time of the donation.

(3) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, nor the amount or nature of the items or services, a condition of doing business with the donor.

(4) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items and services, is determined in a manner that is directly related to the volume or value of referrals or other business generated between the parties. For the purposes of this paragraph, the determination is deemed not to be directly related to the

volume or value of referrals or other business generated between the parties if any one of the following conditions is met:

(i) The determination is based on the total number of prescriptions written by the recipient;

(ii) The determination is based on the size of the recipient's medical practice (for example, total patients, total patient encounters, or relative value units);

(iii) The determination is based on the total number of hours that the recipient practices medicine;

(iv) The determination is based on the recipient's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);

(v) The determination is based on whether the physician is a member of the hospital's medical staff, if the donor is a hospital; or

(vi) The determination is made in any reasonable and verifiable manner that is not directly related to the volume or value of referrals or other business generated between the parties.

(5) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items or services being provided and the value of those items and services;

(iii) Covers all of the electronic health records items and services to be furnished by the entity to the physician; and

(iv) Contains 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.

(6) The entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the fact that the physician possessed or had obtained items and services that were technically or functionally equivalent to those donated by the donor.

(7) For items or services that are of the type that can be used for any patient without regard to payor status, the donor may not restrict or take any action to limit the physician's right or ability to use the items or services for any patient.

(8) The items and services do not include staffing of physician offices and are not used solely to conduct personal

business or business unrelated to the physician's medical practice.

(9) The electronic health records technology contains electronic prescribing capability that complies with the electronic prescription drug program standards under Medicare Part D at the time the items and services are furnished.

(10) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 18, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 12, 2005.

Michael O. Leavitt,

Secretary.

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