

(2) *Determining medical improvement and its relationship to your abilities to do work.*

* * * (In addition, see paragraph (b)(8) of this section if you work during your current period of eligibility based on disability or during certain other periods.) * * *

* * * * *

(5) *Evaluation steps.* * * * The steps are as follows. (See paragraph (b)(8) of this section if you work during your current period of eligibility based on disability or during certain other periods.)

* * * * *

(8) *If you work during your current period of eligibility based on disability or during certain other periods.*

(i) We will not consider the work you are doing or have done during your current period of eligibility based on disability (or, when determining whether you are eligible for expedited reinstatement of benefits under section 1631(p) of the Act, the work you are doing or have done during or after the previously terminated period of eligibility referred to in section 1631(p)(1)(B) of the Act) to be past relevant work under paragraph (b)(5)(vi) of this section or past work experience under paragraph (b)(5)(vii) of this section. In addition, if you are currently entitled to disability benefits under title II of the Social Security Act, we may or may not consider the physical and mental activities that you perform in the work you are doing or have done during your current period of entitlement based on disability, as explained in paragraphs (b)(8)(ii) and (iii).

(ii) If you are currently entitled to disability insurance benefits as a disabled worker, child's insurance benefits based on disability, or widow's or widower's insurance benefits based on disability under title II of the Social Security Act, and at the time we are making a determination on your case you have received such benefits for at least 24 months, we will not consider the activities you perform in the work you are doing or have during your current period of entitlement based on disability if they support a finding that your disability has ended. (We will use the rules in § 416.990(i)(2) to determine whether the 24-month requirement is met.) However, we will consider the activities you do in that work if they support a finding that your disability continues or they do not conflict with a finding that your disability continues. We will not presume that you are still disabled if you stop working.

(iii) If you are not a person described in paragraph (b)(8)(ii) of this section, we

will consider the activities you perform in your work at any of the evaluation steps in paragraph (f) of this section at which we need to assess your ability to function.

* * * * *

Subpart N—Determinations, Administrative Review Process, and Reopening of Determinations and Decisions

12. The authority citation for subpart N continues to read as follows:

Authority: Secs. 702(a)(5), 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1383, and 1383b).

13. Section 416.1403 is amended by removing the word “and” at the end of paragraph (a)(20), replacing the period at the end of paragraph (a)(21) with “; and”, and adding new paragraph (a)(22) to read as follows:

§ 416.1403 Administrative actions that are not initial determinations.

(a) * * *

(22) Starting or discontinuing a continuing disability review.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of Inspector General

42 CFR Part 1001

RIN 0991–AB39

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

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Proposed Rule.

SUMMARY: As required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, this proposed rule would establish a new safe harbor under the Federal anti-kickback statute for certain arrangements involving the provision of electronic prescribing technology. Specifically, the safe harbor would protect certain arrangements involving hospitals, group practices, and prescription drug plan (PDP) sponsors and Medicare Advantage (MA) organizations that provide to specified

recipients certain nonmonetary remuneration in the form of hardware, software, or information technology and training services necessary and used solely to receive and transmit electronic prescription drug information. In addition, using our separate legal authority under section 1128B(b)(3)(E) of the Social Security Act (the “Act”), we are also proposing separate safe harbor protection for certain 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 assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on December 12, 2005.

ADDRESSES: You may submit comments by any of the methods set forth below. In all cases, when commenting, please refer to file code **OIG–405–P**.

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

Please allow sufficient time for us to receive mailed comments by the due date in the event of delivery delays.

- Hand delivery/courier—Office of Inspector General, Department of Health and Human Services, Attention: **OIG–405–P**, Room 5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

Because access to the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in **OIG's** drop box located in the main lobby of the building.

- Federal eRulemaking Portal: <http://www.regulations.gov>. Include agency name and identifier **RIN 0991–AB36**.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. For information on viewing public comments, see section V of the Supplementary Information section preamble.

FOR FURTHER INFORMATION CONTACT: Catherine Martin, Office of Counsel to the Inspector General, (202) 619–0335.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Anti-Kickback Statute and Safe Harbors

Section 1128B(b) of the Act (42 U.S.C. 1320a-7b(b), the anti-kickback statute) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under any of the Federal health care programs, as defined in section 1128B(f) of the Act. The offense is classified as a felony and is punishable by fines of up to \$25,000 and imprisonment for up to five years. Violations of the anti-kickback statute may also result in the imposition of civil money penalties (CMPs) under section 1128A(a)(7) of the Act (42 U.S.C. 1320a-7a(a)(7)), program exclusion under section 1128(b)(7) of the Act (42 U.S.C. 1320a-7(b)(7)), and liability under the False Claims Act, (31 U.S.C. 3729-33).

The types of remuneration covered specifically include, without limitation, kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, in cash or in kind. In addition, prohibited conduct includes not only the payment of remuneration intended to induce or reward referrals of patients, but also the payment of remuneration intended to induce or reward the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by any Federal health care program.

Because of the broad reach of the statute, concern was expressed that some relatively innocuous commercial arrangements were covered by the statute and, therefore, potentially subject to criminal prosecution. In response, Congress enacted section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93 (section 1128B(b)(3)(E) of the Act), which specifically required the development and promulgation of regulations, the so-called "safe harbor" provisions, that would specify various payment and business practices that would not be treated as criminal offenses under the anti-kickback statute, even though they may potentially be capable of inducing referrals of business under the Federal health care programs. Since July 29, 1991, we have published in the **Federal Register** a series of final regulations establishing "safe harbors" in various areas.¹ These OIG safe harbor

provisions have been developed "to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements." (56 FR 35952, 35958; July 21, 1991).

Health care providers and others may voluntarily seek to comply with safe harbors so that they have the assurance that their business practices will not be subject to any enforcement action under the anti-kickback statute, the CMP provision for anti-kickback violations, or the program exclusion authority related to kickbacks. In giving the Department of Health and Human Services the authority to protect certain arrangements and payment practices under the anti-kickback statute, Congress intended the safe harbor regulations to be evolving rules that would be updated periodically to reflect changing business practices and technologies in the health care industry.

B. Section 101 of MMA

Section 101 of the MMA added a new section 1860D to the Act, establishing a Part D prescription drug benefit in the Medicare program. As part of the new statutory provision, Congress, through section 1860D-4(e) of the Act, directed the Secretary to create 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.² Section 1860D-4(e)(6) of the Act directs the Secretary, in consultation with the Attorney General, to create a safe harbor to the anti-kickback statute that would protect certain arrangements involving the provision of nonmonetary remuneration (consisting of items and services in the form of hardware, software, or information technology or training services) that is necessary and used solely to receive and transmit electronic prescription drug information in accordance with electronic prescribing standards promulgated by the Secretary under section 1860D-4(e)(4) of the Act. Specifically, the safe harbor would set forth conditions under which the provision of such remuneration by hospitals, group practices, and PDP sponsors and MA organizations (collectively, for purposes of this preamble discussion, "Donors") to prescribing health care professionals, pharmacies, and pharmacists (collectively, for purposes of this

preamble discussion, "Recipients") would be protected.

The OIG has a longstanding concern about the provision of free or reduced price goods or services to an existing or potential referral source. There is a substantial risk that free or reduced price goods or services may be used as a vehicle to disguise or confer an unlawful payment for referrals of Federal health care program business. Financial incentives offered, paid, solicited, or received in exchange for generating Federal health care business increase the risks of, among other problems: (i) Overutilization of health care items or services; (ii) increased Federal program costs; (iii) corruption of medical decision making; and (iv) unfair competition. Consistent with the structure and purpose of the anti-kickback statute and the regulatory authority at section 1128B(b)(3)(E) of the Act, we believe any safe harbor for electronic prescribing arrangements should protect innocuous or beneficial arrangements that would eliminate perceived barriers to the adoption of electronic prescribing without creating undue risk that the arrangement might be used to induce or reward the generation of Federal health care program business.

We do not believe Congress, in enacting section 1860D-4(e)(6) of the Act, intended to suggest that a new safe harbor is needed for all or even most arrangements involving the provision of electronic prescribing items and services. In general, fair market value arrangements that are arm's-length and do not take into account the volume or value of Federal health care program referrals, or arrangements that do not have as one purpose the generation of business payable by a Federal health care program, should not raise concerns under the anti-kickback statute. Simply put, absent the requisite intent, the anti-kickback statute is not violated. In addition, many arrangements can be structured to fit in existing safe harbors, including the safe harbors for discounts (42 CFR 1001.952(h)) and for remuneration offered to employees (42 CFR 1001.952(i)). Finally, parties may use the OIG advisory opinion process (42 CFR part 1008; <http://oig.hhs.gov/fraud/advisoryopinions.html>) to determine whether their particular arrangements would be subject to OIG sanctions.

In addition to the new safe harbor under the anti-kickback statute, section 1860D-4(e)(6) of the Act directs the Secretary to create a corresponding exception to section 1877 of the Act, commonly known as the physician self-referral law. That exception is being

¹ 56 FR 35952 (July 29, 1991); 61 FR 2122 (January 25, 1996); 64 FR 63518 (November 19,

1999); 64 FR 63504 (November 19, 1999); and 66 FR 62979 (December 4, 2001).

² See H.R. Conf. Rep. No. 108-391, 495 (2003).

promulgated through a separate rulemaking by the Centers for Medicare & Medicaid Services (CMS), the agency that administers the physician self-referral law. We have endeavored to ensure as much consistency as possible between our proposed safe harbor and the corresponding exception proposed by CMS, given the differences in the respective underlying statutes. We intend the final rules to be similarly consistent. One significant difference in the statutory schemes is that fitting in an exception under section 1877 is mandatory, whereas complying with a safe harbor under the anti-kickback statute is voluntary. In other words, arrangements that do not comply with the electronic prescribing safe harbor will not necessarily be illegal under the anti-kickback statute. Rather, they will be subject to the customary case-by-case review under the statute. Another difference is that section 1877 applies only to referrals from physicians, while the anti-kickback statute applies more broadly.

In certain respects, we are considering safe harbor standards that might impose

stricter conditions than the corresponding exception to section 1877. In part, this reflects the separate purposes of the anti-kickback statute and section 1877, as well as the serious nature of the felony violation described by the anti-kickback statute. In essence, section 1877 of the Act sets a minimum standard for acceptable financial arrangements; the anti-kickback statute addresses residual risk that may be posed by arrangements that otherwise comply with a physician self-referral exception. As explained in the Phase I final physician self-referral rule promulgated by CMS, "many relationships that may not merit blanket prohibition under section 1877 of the Act can, in some circumstances and given necessary intent, violate the anti-kickback statute." (66 FR 856, 863; January 4, 2001).

II. Provisions of the Proposed Rule

This proposed rule would add a new paragraph (x) to the existing safe harbor regulations at 42 CFR 1001.952. This new paragraph (x) would describe more specifically the items and services

protected by the new safe harbor for prescribing drugs electronically; the individuals and entities that may provide the protected items and services; and the conditions under which providing the items and services to prescribing health care professionals, pharmacies, and pharmacists would be protected. In addition, using our separate legal authority at § 1128B(b)(3)(E) of the Act, as discussed below, we are proposing separate safe harbor protection for certain electronic health records software not covered by the MMA mandated safe harbor for electronic prescribing. These proposed safe harbors would, if promulgated, create separate and independent grounds for protection under the anti-kickback statute. For the convenience of the public, we are providing the following chart that lays out schematically the overall structure and approach of these proposals, details of which are provided below in Sections II. A and B. Readers are cautioned that the proposals contain additional conditions and information not summarized here.

	MMA-mandated electronic prescribing safe harbor	Pre-interoperability electronic health records safe harbor	Post-interoperability electronic health records safe harbor
Authority for Proposed Exception ..	Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.	Section 1128B(b)(3)(E) of the Social Security Act.	Section 1128B(b)(3)(E) of Social Security Act.
Covered Technology	<i>Proposed:</i> • 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> • 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> • <i>Certified</i> 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> • Foundation standards for electronic prescribing as adopted by the Secretary.	<i>Proposed:</i> • Electronic prescribing component must comply with foundation standards for electronic prescribing as adopted by the Secretary.	<i>Proposed:</i> • 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> • As required by statute, permissible donors are hospitals (to members of their medical staffs), group practices (to physician members), PDP sponsors and MA organizations (to network pharmacists and pharmacies, and to prescribing health care professionals).	<i>Proposed:</i> • Hospitals to members of their medical staffs. • Group practices to physician members. • PDP sponsors. • MA organization.	<i>Proposed:</i> • Hospitals to members of their medical staffs. • Group practices to physician members. • PDP sponsors. • MA organization.

	MMA-mandated electronic prescribing safe harbor	Pre-interoperability electronic health records safe harbor	Post-interoperability electronic health records safe harbor
Selection of Recipients	<i>Proposed:</i> Donors may not take into account the volume or value of referrals from the recipient or other business between the parties.	<i>Proposed:</i> Donors may not take into account the volume or value of referrals from the recipient or other business between the parties.	<i>Proposed:</i> 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> No specific dollar amount proposed for a cap on the value of protected technology.	<i>Proposed:</i> No specific dollar amount proposed for a cap on the value of protected items and services.	<i>Proposed:</i> - No specific dollar amount proposed for a cap on the value of protected items and services. - May be greater than the cap on pre-interoperability donations.

A. Electronic Prescribing Safe Harbor Required Under Section 101 of the MMA: Paragraph (x)

1. Protected Nonmonetary Remuneration

Section 1860D–4(e)(6) of the Act authorizes the creation of a safe harbor for the provision of items and services that are “necessary and used solely” to receive and transmit electronic prescription drug information. This proposed rule would clarify the items and services that would qualify for the new safe harbor (for purposes of this preamble discussion, “qualifying electronic prescribing technology”).

“Necessary” nonmonetary remuneration—First, consistent with the MMA mandate, the proposed safe harbor would protect 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. However, the safe harbor would not protect arrangements in which a Donor provides items or services that are technically or functionally equivalent to items and services the Recipient currently possesses or has obtained. Thus, for example, under the proposed regulations, a Donor can provide a hand-held device capable of transmitting electronic prescribing information to the Recipient, even if the Recipient already has a desktop computer that could be used to transmit or receive the same information, because the mobility allowed by the hand-held device offers a material advantage over the desktop computer for Recipients who would use the device portably. By contrast, the provision of a second hand-held device would not qualify for safe harbor

protection if the Recipient already has a hand-held device sufficient to run the requisite electronic prescribing 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 restricting the exception to “necessary” items and services is important to minimize the potential for abuse. However, we recognize that Donors will not necessarily know which items and services the Recipient already possesses or has obtained. Accordingly, proposed § 1001.952(x)(7)(iv) would require the Recipient to certify that the items and services to be provided are not technically or functionally equivalent to items or services the Recipient already possesses or has obtained. The certification would need to be updated prior to the provision of any necessary upgrades or items and services not reflected in the original certifications. 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 Recipients simply execute a form certification provided by a Donor. Therefore, we are proposing at § 1001.952(x)(8) that the Donor must not have actual knowledge of, and not act in reckless disregard or deliberate ignorance of, the fact that the Recipient possesses or has obtained items and services that are technically or functionally equivalent to those donated by the Donor. The Recipient would be protected only if the certification is truthful. We are soliciting comments about other ways to address this concern.

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

“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 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. For example, a computer that a physician can use to conduct office or personal business might have value to the physician apart from its electronic prescribing purpose; if this value is transferred to the physician in connection with referrals, the statute would be implicated.³ Accordingly, the proposed safe harbor requires that the protected items and services be used solely to transmit or receive electronic prescribing information.

We are concerned that Donors might provide software for free or reduced cost 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 safe harbor; such arrangements potentially raise significant concerns under the anti-kickback statute, if any purpose of the provision of the bundled software is to induce or reward the generation of Federal health care program business. However, the Recipient would not be precluded from purchasing for fair market value additional technology not protected by the proposed safe harbor.

We are mindful that hardware and connectivity services can be used for the receipt and transmission of a wide range

³ See, e.g., 56 FR 35952, 35978 (July 29, 1991) noting that a computer that has independent value to a physician may constitute an illegal inducement.

of information services, including, but not limited to, electronic prescription information, and that many people may prefer to use a single, multi-functional device, especially a hand-held, rather than multiple single-use devices. Similarly, many people may prefer to use a single connectivity service. Accordingly, we are proposing using our regulatory authority under section 1128B(b)(3)(E) of the Act to create an additional safe harbor to protect the provision by Donors to Recipients of some limited hardware (including necessary operating system software) and connectivity services that are used for more than one function, so long as a substantial use of the item or service is to receive or transmit electronic prescription information. We propose to treat operating software as integral to the hardware and distinct from other software applications that are not necessary for the hardware to operate.

Protection under this additional, separate safe harbor would not extend to the provision of items or services that are only occasionally used for electronic prescribing. The additional safe harbor would incorporate the definitions and conditions set forth in this proposed rulemaking for the MMA-mandated safe harbor 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 safe harbor 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 are also soliciting public comment on the nature and amount of any cap that we might impose on the value of the donated multi-functional hardware or connectivity services.

2. Donors and Recipients Protected by the Proposed Safe Harbor

Section 1860D–4(e)(6) of the Act describes the parties that may be protected under the new safe harbor. Specifically, protection is afforded to: (1) Hospitals with respect to members of their medical staffs; (2) group practices with respect to prescribing health care professionals who are members of the group practice; and (3) PDP sponsors and MA organizations with respect to participating pharmacists and pharmacies, as well as prescribing

health care professionals. We address each category below.

Hospitals/Medical Staff—Proposed § 1001.952(x)(1)(i) would protect donations of qualifying electronic prescribing technology provided by a hospital to physicians on its medical staff. We do not intend to interpret this provision as extending to physicians who do not routinely furnish services at the hospital. We do not intend for this exception to protect remuneration that is used to induce physicians who already use other hospitals to join the medical staff of a different hospital. We are soliciting public comment on whether we should include items or services provided to other individuals or entities (e.g., other health care prescribing professionals who treat patients at the hospital).

Group Practices/Members—Proposed § 1001.952(x)(1)(ii) would protect donations of qualifying electronic prescribing technology provided by a group practice to its members who are prescribing health care professionals. For consistency with the regulations promulgated in accordance with section 1877 of the Act, we propose to interpret the terms “group practice” and “members” of a group practice consistent with existing definitions in section 1877(h)(4) of the Act and the regulations at 42 CFR 411.352 and 42 CFR 411.351, respectively. Those provisions make clear that a “group practice” must be a single legal entity with unified business operations and may not be an informal affiliation of physicians and that a “member” of a group practice refers to a physician-owner or physician-employee of the group practice. A “member” of the group practice, under § 411.351 does not include independent contractors of the group or persons who are not physicians.

Because section 1877 of the Act deals only with physician referrals, application of its definition of a “member” of a group practice is not sufficient to define the full range of “prescribing health care professionals” included in section 1860D–4(e)(6) of the Act, and it is necessary for us to augment the definition in this proposed rule. Accordingly, for purposes of the proposed safe harbor, “prescribing health care professionals who are members of the group” would include prescribing professionals (e.g., nurse practitioners) who are owners or employees of the group and who are authorized to prescribe under applicable State licensing laws.

Because the definition of “member” of the group practice under § 411.351 excludes independent contractors, we

are soliciting comments regarding whether and how a group practice may appropriately furnish qualifying electronic prescribing technology to physicians or other prescribing health care professionals who contract with the group to furnish services to the group’s patients.

We do not believe that the inclusion by Congress of group practices and their members in section 1860D–4(e)(6) of the Act was intended to imply that the provision of qualifying electronic prescribing technology by a group practice to its members necessarily required a new safe harbor under the anti-kickback statute. In many circumstances, the provision of equipment or other resources by a medical group to its member health care professionals for use in furnishing services to the group’s patients would not raise fraud and abuse concerns under the anti-kickback statute. Moreover, for those situations where the statute may be implicated, many arrangements can be structured to fit in an existing safe harbor, including, for example, the safe harbors for personal services and management contracts or employee compensation at § 1001.952(d) and (i), respectively. Arrangements that do not fit in a safe harbor are not necessarily illegal under the anti-kickback statute. We believe Congress included these relationships in section 1860D–4(e)(6) of the Act simply to encourage group practices to adopt electronic prescription technology.

PDP Sponsors and MA Organizations/Pharmacies, Pharmacists, and Prescribing Health Care Professionals—Consistent with section 1860D–4(e)(6) of the Act, proposed § 1001.952(x)(1)(iii) would protect donations of qualifying electronic prescribing technology provided by a PDP sponsor or MA organization to prescribing health care professionals, participating pharmacies, and participating pharmacists. We propose to interpret the term “PDP sponsor” and “MA organization” consistent with the Medicare Prescription Drug Benefit regulations at 42 CFR 423.4 and 42 CFR 422.2, respectively. We propose to interpret the terms “pharmacy” and “pharmacist” consistent with applicable State licensing laws. We propose to interpret “prescribing health care professionals” as physicians or other health care professionals (e.g. nurse practitioners) licensed to prescribe drugs in the State in which the drugs are dispensed.

Finally, we are soliciting comments on whether there is a need to protect other categories of Donors or Recipients, beyond those specifically set forth in

section 1860D–4(e)(6) of the Act, and if so, how best to address safe harbor protection for those individuals or entities. In particular, we are interested in comments addressing the types of 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. In general, we believe that only individuals and entities involved in the ordering, processing, filling, or reimbursing of prescriptions are likely to have sufficient need to justify inclusion in an electronic prescribing safe harbor.

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

Promoting Compatibility and Interoperability—Section 1860D–4(e)(6) of the Act is integral to the electronic prescribing drug program established by section 101 of MMA. Section 1860D–4(e)(6) of the Act provides that, in order to qualify for the safe harbor, 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 the Part D electronic prescription drug program. Consistent with section 1860(D)–4(e)(6) of the Act, proposed § 1001.952(x)(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 safe harbor should protect qualifying electronic prescription technology that is used for the transmission of prescription information regarding items and services that are not drugs (e.g., supplies or laboratory tests).

We believe that interoperability can serve as an important safeguard against fraud and abuse and mitigate the risk that a Donor's offer of free or reduced price technology to a Recipient could be a means of maintaining or increasing referrals from the Recipient. With interoperable electronic prescribing technology, the Recipient 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 prescription drug program.

To the extent that either the hardware or software can be interoperable, the

proposed regulation at § 1001.952(x)(3) would 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 Donors to use the provision of electronic prescribing technology to tie Recipients to the Donor. We are considering defining the term “interoperable” in this context to mean the ability of different operating and software systems, applications, and networks to communicate and exchange data 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.

Value of protected technology—To further safeguard against fraud and abuse, we believe it would be appropriate to limit the aggregate value of the qualifying electronic prescribing technology that a Donor could provide to a Recipient under the safe harbor. We are considering whether to limit the aggregate fair market value of all items and services provided to a Recipient from a single Donor. We 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.

In addition, we are interested in public comments that address the retail and nonretail costs (i.e., the costs of purchasing from manufacturers, distributors, or other nonretail sources) of obtaining electronic prescribing technology and the degree to which potential Recipients may already possess items or services that could be used for electronic prescribing. We note that CMS has received varying estimates of the costs of implementing electronic prescribing through the comment

process for the CMS E-Prescribing and the Prescription Drug Program proposed rule published on February 4, 2005 in the **Federal Register** (70 FR 6256). 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. While 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.

We are considering various potential caps that would be no higher than any cap that may ultimately be imposed in the corresponding electronic prescribing exception under Section 1877 of the Act to be promulgated by CMS. We are considering measuring the monetary limit at fair market value to the Recipient (i.e., the retail value). We believe this approach is consistent with the anti-kickback statute's intent requirement 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 considering setting an initial cap, which would be lowered after a certain period of time sufficient to promote the initial adoption of the technology. This would have the effect of encouraging investments in the desired technology while also ensuring that, once the technology has been widely adopted and its costs have come down, the safe harbor cannot be abused to disguise payments for referrals. We are soliciting public comment about this approach. Finally, we are soliciting comments on whether and, if so, how to take into account Recipient access to any software that is publicly available either free or at a reduced price.

Other Conditions—Proposed §§ 1001.952(x)(5), (x)(6), and (x)(7) would incorporate additional conditions. Paragraph § 1001.952(x)(5) would provide that the Recipients (including their groups, employees, or staff) may not make the donation of qualifying electronic prescribing technology from Donors a condition of doing business with the Donor. Paragraph (x)(6) would provide that neither the eligibility of a Recipient to receive items and services from a protected Donor, nor the amount or nature of the items or services received, may be determined in a manner that

takes into account the volume or value of the Recipient's referrals or other business generated between the parties. This would not preclude selection criteria that are based upon the total number of prescriptions written by a Recipient, but would preclude criteria based upon the number or value of prescriptions written by the Recipient 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 safe harbor would not protect arrangements that seek to induce a Recipient to change loyalties from other providers or plans to the Donor (e.g., 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 § 1001.952(x)(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 their values, and to include the certification described in section II.A.1 above. To permit effective oversight of protected arrangements, the writing must cover all qualifying electronic prescribing technology provided by the Donor (or affiliated parties) to the Recipient. For example, if a Donor provides a piece of hardware under one arrangement and 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).

Finally, 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 recipients 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 transmits prescriptions to pharmacies) is potentially usable for all

patients, and recipients should not be restricted from using such technology for all patients. Accordingly, proposed § 1001.952(x)(4) would require that, where possible, recipients must be able to use the protected technology for all patients without regard to payor status.

B. Proposed Electronic Health Records Safe Harbors

Many in the hospital industry, among others, have raised the issue of the need for safe harbor protection for arrangements involving technology other than electronic prescribing. In many cases, such arrangements may qualify for safe harbor protection under existing safe harbors, such as the employee safe harbor (42 CFR 1001.952(i)), the discounts safe harbor (42 CFR 1001.952(h)), or the equipment rental safe harbor (42 CFR 1001.952(c)). Moreover, as explained above, arrangements that do not qualify for safe harbor protection are not necessarily illegal.

In general, the provision of valuable technology to physicians or other sources of Federal health care program referrals poses a heightened risk of fraud or abuse. This risk increases as the value of the technology to the Recipient increases. In the preceding discussion of the proposed safe harbor for electronic prescribing technology, we noted a number of fraud and abuse risk areas; those risk areas would also apply to the provision of free or reduced price electronic health records technology. In many respects, the provision of electronic health records technology to physicians and others poses greater risk of fraud or abuse than the provision of electronic prescribing technology; electronic health records technology is inherently more valuable to physicians in terms of actual cost, avoided overhead, and administrative expenses of an office practice.

Notwithstanding, we believe it may be possible to craft safe harbor conditions that would promote 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 serve as marketing platforms or mechanisms to influence inappropriately clinical decision making or tie physicians to particular providers or suppliers. The potential benefits of interoperable and certified electronic health records technology are discussed in detail in the preamble to CMS' contemporaneous notice of proposed rulemaking for an exception under section 1877 and are not repeated

here. Full interoperability of electronic health records technology would help reduce, but not eliminate, some risks of program and patient fraud and abuse (such as improper patient steering) by ensuring that donors would not be able to lock recipients into using the donor's systems.

Currently, uniform interoperability standards for electronic health records and certification requirements necessary to ensure interoperability do not exist. Accordingly, we are considering an incremental approach to safe harbor protection in this area. Specifically, we are proposing using our legal authority at section 1128B(b)(3)(E) of the Act to promulgate two safe harbors related to electronic health records software and directly related training services that are necessary and used to receive, transmit, and maintain electronic health records of the entity's or physician's patients. The first safe harbor would apply to donations made before adoption by the Secretary of product certification criteria, including criteria for interoperability, functionality, and privacy and security of electronic health records technology. These conditions are also referred to herein as "product certification criteria." (For purposes of this rulemaking, this safe harbor will be referred to as the "pre-interoperability" safe harbor.) Once standards are identified and product certification criteria are developed for electronic health records and adopted by the Secretary, we believe some enhanced flexibility in the conditions applicable under a safe harbor for electronic health records may be appropriate, provided the safe harbor conditions as a whole sufficiently guard against fraud and abuse. A second safe harbor would apply to donations made after product certification criteria have been adopted. (For purposes of this rulemaking, this second safe harbor will be referred to as the "post-interoperability" safe harbor.) The post-interoperability safe harbor would recognize the reduction in the risk of fraud and abuse that may result from the ability to ensure that free or reduced price products provided under the safe harbor are interoperable and certified.

Unlike electronic prescribing, Congress provided no direction with respect to any safe harbor for electronic health records. As discussed more fully below, any safe harbor of electronic health records technology will necessarily involve consideration of a number of important variables. Given this, as well as the inherent risk of fraud and abuse typically posed by gifts of free items and services to potential referral sources, we believe we do not

have sufficient information at this time to draft appropriate safe harbor language. However, we are soliciting public comments on the proposed scope and conditions for electronic health records safe harbors, as outlined below.

1. Proposed Pre-Interoperability Safe Harbor

We are considering incorporating the following features in the pre-interoperability safe harbor.

Covered Technology—The pre-interoperability safe harbor would protect electronic health records software (that is, software that is essential to and used solely for the transmission, receipt, and maintenance of patients' electronic health records and electronic prescription drug information) and directly-related training services, provided that the software includes 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 standards established by the Secretary under the Part D electronic prescription drug program. We are soliciting comments on whether the exception should permit the electronic prescribing component of electronic health records 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 require that electronic health records software include a computerized provider order entry ("CPOE") component. The pre-interoperability safe harbor would not protect the provision of other types of technology, including, but not limited to, hardware, connectivity services, billing, scheduling, or other similar general office management or administrative software services, or software that might be used by a Recipient to conduct personal business or business unrelated to the Recipient's medical practice. While we would protect necessary training services in connection with the software, we would not protect the provision of staff to Recipients 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.

Any safe harbor would need to define "electronic health records." As with

electronic prescribing technology, we are interested in public comments that address the software functions that should be included in the definition of "electronic health records"; the types of software that should be protected; the retail and nonretail cost of such software; the manner in which such software is currently marketed; methods for defining the scope of protected software; and safeguards that might be imposed (either by definition or separately) to ensure that provision of the software cannot be used to camouflage unlawful payments for referrals or to tie impermissibly Recipients to Donors in a position to benefit from the Recipient's referrals.

The pre-interoperability safe harbor would require that the protected software and training services be "necessary" consistent with our interpretation of the term in section II.A.1, and we are considering including comparable documentation provisions, including comparable certifications by Recipients, to ensure that the safe harbor does not protect the provision of items or services that are technically or functionally equivalent to items and services the Recipient currently possesses or has obtained. As with electronic prescribing technology, we are concerned that there may be a risk that Recipients would intentionally divest themselves of functionally or technically equivalent technology that they already possess to shift costs to Donors, and we are soliciting public comments on whether and how to address this situation.

Interoperability—In addition to requiring that the electronic prescribing component of the protected software comply with standards established by the Secretary for the Part D electronic prescription drug program, it would be important that neither Donors 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 that protected software comply with relevant Public Health Information Network preparedness standards, such as those related to BioSense. We are soliciting comments on these and other appropriate qualifications. In addition, electronic health records lack the program and beneficiary protections that exist under the Part D prescription drug program and related electronic prescription standards. We are considering including in the final safe harbor conditions designed to replicate these protections for electronic health records, including quality assurance measures. We are soliciting public

comments on the most appropriate way to do so.

Value of the Protected Technology—As with electronic prescribing, we are proposing limiting the aggregate value of the protected software and training services that a Donor could provide to a Recipient. The limit under the proposed pre-interoperability safe harbor would be directly related to the limit adopted in connection with the electronic prescribing safe harbor discussed at II.A.3. There, we note various alternatives we are considering in connection with a limiting cap and outline issues about which we are soliciting public comments. We are considering similar alternatives, and are interested in similar comments, in connection with a safe harbor for electronic health records. Given that electronic health records technology has high value to Recipients, we are considering several approaches, including: (1) An aggregate dollar cap; (2) a cap that would be set at a percentage of the value of the technology to the Recipient (thus requiring Recipients to share a portion of the costs and reducing windfall benefits to Recipients); or (3) a cap set at the lower of a fixed dollar amount or a percentage of the value of the technology to the Recipient.

We are soliciting comments on how a cap under a safe harbor for electronic health records would relate to a cap under proposed § 1001.952(x) and how the value of technology provided under the final safe harbors would be aggregated. We are concerned that Donors 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 Recipients 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 considering requiring an overall cap on the value of donated technology (such that the value of technology donated under the electronic prescribing safe harbor would count towards the total value of the software protected under the pre-interoperability safe harbor), as well as documentation requirements that integrate all technology provided under any safe harbor.

Another concern, particularly in light of the cost of electronic health records technology, is that Donors may attempt

to shift the financial burden of providing electronic health records technology to the Federal health care programs or beneficiaries. Accordingly, we would likely include a safe harbor condition that would prohibit such cost shifting. Finally, we are soliciting comments on whether and, if so, how to take into account Recipient access to any software that is publicly available either free or at a reduced price.

Donors and Recipients—The pre-interoperability safe harbor would protect the same categories of Donors and Recipients as the proposed § 1001.952(x)(1) and would define them similarly. 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 safe harbor 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, have a comparable stake in advancing the goal of interoperable electronic health records for patients. In our experience, laboratories and others have used free or deeply discounted goods, such as computers and fax machines, to influence referrals improperly. Longstanding OIG guidance makes clear that gifts of equipment to referral sources that have value to the physicians are highly suspect under the anti-kickback statute.⁴ We are interested in comments regarding whether other categories of Donors or Recipients 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.

Other Conditions—Finally, to further reduce the risk of fraud and abuse, we would incorporate in the pre-interoperability safe harbor for electronic health records certain other conditions described above in connection with proposed § 1001.952(x). These conditions would include the requirement at proposed 1001.952(x)(6) that neither the eligibility

of a recipient to receive items and services from a donor, nor the amount and nature of the items and services received, may 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. In addition, we would include the proposed anti-solicitation provision (§ 1001.952(x)(5)), the proposed documentation requirements (§ 1001.952(x)(7)), and the proposed all-payers requirement (§ 1001.952(x)(4)).

Sunset Provision—We are considering whether to sunset the pre-interoperability safe harbor discussed here once the post-interoperability safe harbor discussed in the next section becomes effective.

Our intent is that the proposed pre-interoperability safe harbor outlined above would promote the adoption of open, interconnected, interoperable electronic health records and electronic prescribing systems. We are interested in comments addressing whether this pre-interoperability safe harbor protection 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.

2. Proposed Post-Interoperability Safe Harbor

The adoption of uniform interoperability standards for electronic health records, as well as product certification criteria to ensure that products meet those standards, will help prevent certified technology from being used by unscrupulous parties to lock in streams of referrals or other business. While interoperability does not vitiate the risk (we are concerned that parties may use the offer or grant of free technology itself as a vehicle to capture referrals), it may mitigate the risk sufficiently to warrant different or modified safe harbor conditions. It would be important that the protected electronic health records software be certified in accordance with product certification criteria adopted by the Secretary, and that the electronic prescribing component 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. Once product certification criteria are adopted for interoperable electronic health records technology, we intend to finalize a post-interoperability safe harbor.

In particular, we are considering a post-interoperability safe harbor that would include the conditions described above in section II.B.1 in connection with the pre-interoperability safe harbor, with the following differences. First, we are considering whether the safe harbor should protect additional software applications, provided electronic prescribing and electronic health records are the core functions of the protected software. 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. As with the pre-interoperability safe harbor, technology protected under this safe harbor must include an electronic prescribing component and may not be used by a Recipient solely to conduct personal business or business unrelated to the Recipient's medical practice. We are soliciting public comments with respect to whether we should also or instead require that electronic health records software include a CPOE component. We are also soliciting public comments on what types of software should be protected under the safe harbor and methods for ensuring that electronic prescribing and electronic health records are the core functions of the donated technology.

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

Third, in light of the enhanced protection against some types of fraud and abuse offered by certified, interoperable systems, we are considering permitting 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 referrals or other business generated between the parties. We are considering enumerating several selection criteria

⁴ See supra note 3.

which, if met, would be deemed not to be directly related to the volume or value of referrals or other business generated between the parties (for example, a determination based on the total number of hours that the recipient practices medicine or a determination based on the size of the recipient's medical practice). Selection criteria that are based upon the total number of prescriptions written by a Recipient would not be prohibited, but the proposed regulation would prohibit criteria based upon the number or value of prescriptions written by the Recipient that are dispensed or paid by the Donor, as well as any criteria directly based on any other business generated between the parties. The safe harbor would not protect arrangements that seek to induce a Recipient to change loyalties from other providers or plans to the Donor. We are soliciting public comments on criteria for selecting recipients of the donated technology.

We expect that this approach would ensure that donated technology can be targeted at Recipients who use it the most in order to promote a public policy favoring adoption of electronic health records, while discouraging problematic direct correlations with Federal health care program referrals (for example, a hospital offering a physician 10 new computers for every 500 referrals of Medicare-payable procedures.) This approach would be a deliberate departure from other safe harbors based on the unique public policy considerations surrounding electronic health records and the Department's goal of encouraging widespread adoption of interoperable electronic health records. We caution, however, that outside of the context of electronic health records, as specifically addressed in this proposed rule, both direct and indirect correlations between the provision of free goods or services and the volume or value of referrals or other business generated between the parties are highly suspect under the anti-kickback statute (and may evidence outright violations) and do not meet the requirements of other safe harbors under the statute or 42 CFR 1001.952.

We are interested in public comments about this approach to selecting Recipients, 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 are appropriate.

Fourth, we are considering a cap on the value of the donated interoperable software that may be larger than the cap under the pre-interoperability safe

harbor. With respect to a limiting cap, we are considering issues similar to those discussed in the preceding sections on the proposed electronic prescribing safe harbor and the proposed pre-interoperability safe harbor, and are interested in comments on those same issues as they might relate to a post-interoperability safe harbor.

In sum, there are a number of ways in which a post-interoperability safe harbor might be structured, and flexibility in one condition might require tightening of another. We are interested in comments on the overall approach outlined above and how the various conditions might be crafted to ensure that the safe harbor conditions, taken as a whole, provide sufficient protection against fraud and abuse.

C. Additional Solicitation of Public Comments: Community-Wide Health Information Systems

The regulations promulgated in accordance with section 1877 of the Act include an exception at 42 CFR 411.357(u) for the provision of information technology items and services by certain entities to physicians to enable the physicians to participate in a community-wide health information system designed to enhance the overall health of the community. The systems must facilitate access to, and sharing of, electronic health care records and any complementary drug information systems, general health information, medical alerts, and related information for patients served by community providers and practitioners. Certain other conditions must also be satisfied. We have received a number of comments in response to our 2004 Annual Solicitation of New Safe Harbors and Special Fraud Alerts (69 FR 71766; December 10, 2004) requesting that we create a comparable safe harbor under the anti-kickback statute. While we have not determined whether such a safe harbor is needed or prudent, we are interested in public comments at this time addressing the need for, and conditions that should pertain to, such a safe harbor. Because of the close relationship between the topic of this proposed rulemaking and the suggested new safe harbor for community-wide health information systems, we believe it appropriate to solicit comments on the latter issue as part of this rulemaking.

III. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866, the Unfunded Mandates Reform Act of 1995, the Regulatory Flexibility

Act (RFA) of 1980, and Executive Order 13132.

Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if 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 must be prepared for major rules with economically significant effects (*i.e.*, \$100 million or more in any given year).

This is not a major rule, as defined at 5 U.S.C. 804(2), and it is not economically significant, since it would not have a significant effect on program expenditures, and there are no additional substantive costs to implement the resulting provisions. This proposed rule would create new safe harbors under the anti-kickback statute for certain entities to provide technology-related items and services to certain parties for electronic prescribing and health record purposes. This proposal would merely create safe harbors under the anti-kickback statute for arrangements under which certain entities would help physicians and certain other individuals and entities with their electronic prescribing and health records expenses. In doing so, this rulemaking would impose no requirements on any party. Parties may voluntarily seek to comply with this provision so that they have assurance that their actions will not subject them to any enforcement actions under the anti-kickback statute. The safe harbors should facilitate the adoption of electronic prescribing and 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 Donors will fund all of the health information technology used by Recipients. However, since we cannot predict which entities will offer these items and services, we cannot determine with certainty the aggregate economic impact of this proposed rulemaking. We do not believe, however, that the impact of this electronic prescribing safe harbor rule would approach \$100 million annually. Therefore, this proposed rule is not a major rule. We note that this proposed rule would remove a perceived 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 qualifying health information technology by hospitals, group practitioners, PDP sponsors, and MA plans, we do not expect that many group practices, PDP sponsors or MA plans would use these proposed safe harbors (and in some cases, existing safe harbors may also be available or parties may use the OIG’s advisory opinion process). Notwithstanding, regardless of whether donations would be allowed under existing safe harbors or those that are included in this proposed rule, we encourage commenters to provide information on the costs that would likely be incurred by Donors that would choose to furnish qualifying health information technology to Recipients, as well as other related costs that would likely be incurred by both Donors and Recipients, 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 the companion proposed physician self-referral exceptions. Furthermore, both the costs and potential savings of electronic prescribing, EHRs, 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 noted in the electronic prescribing proposed rule, which was published on February 4, 2005 (70 FR 6256, 6268–6273), the Department expects 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. Moreover, we have not replicated the extensive analysis of costs, benefits, and potential impact on patient care contained in the companion physician self-referral proposed rule. We believe the analysis set forth there may be similarly relevant to the potential impact of the proposed safe harbors. As also noted there, we assume that qualifying health information technology costs and benefits will be realized sooner or later. 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 for this proposed rule is: to what extent would the use of these proposed anti-kickback safe harbors accelerate adoption of electronic prescribing and EHRs, taking into account available policy instruments, notably the development of interoperable standards? The baseline information is uncertain. As described in more detail in the physician self-referral proposed rule, there are numerous estimates of adoption of electronic prescribing by health plans, hospitals, physicians, and (for prescribing of drugs only) pharmacies. As noted there, these estimates are highly sensitive to assumptions. For example, the maximum allowed remuneration might be as little as half as much or as much as twice as much. The rate of adoption might be higher or lower than estimated. The proportion receiving remuneration could be lower or higher than estimated, depending on willingness of hospitals, group practices, MA organizations and PDP sponsors to subsidize investments in health information technology. We are interested in comments on whether information exists that would allow more definite estimates as to the effects of these proposed safe harbors.

Unfunded Mandates Reform Act

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.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and Government agencies. Most hospitals and most other providers and suppliers are small

entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any one year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this proposed rule would not have a significant impact on small businesses. We base our decision on the fact that we expect the rulemaking on electronic prescribing and health records to be beneficial to the affected entities because it will allow them to better reap the benefits of increased use of electronic prescribing and health records technology, including reduction of medical errors and increased operational efficiencies.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule would not have a substantial negative impact on the operations of a substantial number of small rural hospitals. If this rule has any impact, it would be a substantial positive impact in reducing costly medical errors and increasing operational efficiencies through the use of technology.

Executive Order 13132

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. Since this regulation does not impose any costs on State or local Governments, the requirements of Executive Order 13132 are not applicable.

The Office of Management and Budget (OMB) has reviewed this rule in accordance with Executive Order 12866.

IV. Paperwork Reduction Act

In accordance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we are required to solicit public comments, and receive final OMB approval, on any information collection requirements set forth in rulemaking.

The safe harbors promulgated in this proposed rule impose some minimal

information collection requirements. Specifically, for an arrangement to fall within the proposed safe harbors would have to fulfill the following documentation requirements: (1) There must be a writing signed by the parties; (2) the written agreement must identify the items or services being provided and their values; (3) the written agreement must incorporate or cross-reference prior relevant agreements; and (4) the written agreement must contain a certification by the Recipient that the items and services to be provided do not duplicate any existing items or services the Recipient already has or has obtained from another source.

Compliance with a safe harbor under the Federal anti-kickback statute is voluntary, and no party is ever required to comply with a safe harbor. Instead, safe harbors merely offer an optional framework for structuring business arrangements to ensure compliance with the anti-kickback statute. All parties remain free to enter into arrangements without regard to a safe harbor, so long as the arrangements do not involve unlawful payments for referrals under the anti-kickback statute. Thus, we believe that the documentation requirements necessary to enjoy safe harbor protection do not qualify as an added paperwork burden in accordance with 5 CFR 1320.3(b)(2), because the requirements are consistent with usual and customary business practices and because the time, effort, and financial resources necessary to comply with the requirements would largely be incurred in the normal course of business activities.

We are soliciting public comments with respect to these requirements. Comments on these requirements should be sent to the following address within 60 days following the **Federal Register** publication of this interim final rule:

OIG Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, 725 17th Street, NW., Washington, DC 20053, FAX: (202) 395-6974.

V. Public Inspection of Comments and Response to Comments

Comments will be available for public inspection beginning November 10, 2005 in Room 5518, 330 Independence Avenue, SW., Washington, DC on Monday through Friday of each week (Federal holidays excepted) between the hours of 9 a.m. and 4 p.m., (202) 619-0089.

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able

to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and will respond to the comments in the preamble of the final rule.

List of Subjects in 42 CFR Part 1001

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare.

Accordingly, 42 CFR part 1001 would be amended as set forth below:

PART 1001—[AMENDED]

1. The authority citation for part 1001 would be amended to read as follows:

Authority: 42 U.S.C. 1302, 1320a-7, 1320a-7b, 1395u(j), 1395u(k), 1395w-104(e)(6), 1395y(d), 1395y(e), 1395cc(b)(2)(D), (E) and (F), and 1395hh; and sec. 2455, Pub. L. 103-355, 108 Stat. 3327 (31 U.S.C. 6101 note).

2. Section 1001.952 would be amended by republishing the introductory text, and by adding (x) to read as follows:

§ 1001.952 Exceptions.

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

* * * * *

(x) *Electronic Prescribing Items and Services.* As used in section 1128B of the Act, “remuneration” does not include nonmonetary 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—
- (i) In the case of a hospital, by the hospital to physicians who are members of its medical staff;
- (ii) In the case of a group practice, by the group practice to prescribing health care professionals who are members of the group practice; and
- (iii) In the case of a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization and to prescribing health care professionals.

(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 donor (or any person on the donor'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) With respect to 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 recipient's right or ability to use the items or services for any patient.

(5) The prescribing health care professional, pharmacy, or pharmacist (or any affiliated group, employee, or staff member) does not make the receipt of items or services a condition of doing business with the donor.

(6) Neither the eligibility of a prescribing health care professional, pharmacy, or pharmacist for the items or services, nor the amount or nature of the items or 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 and services to be furnished by the donor (or affiliated parties) to the recipient; and
- (iv) Contains a certification by the recipient that the items and services are not technically or functionally equivalent to items and services the recipient already possesses or has obtained. The recipient will be deemed not to comply with this subparagraph if the certification the recipient provides is not full, complete, and accurate, to the best of the recipient's knowledge.

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

Note to Paragraph (x): For purposes of paragraph (x) of this section, group practice shall have the meaning set forth at § 411.352; members of a group practice shall mean all persons covered by the definition of “member of the group practice” at § 411.351, as well as other prescribing health care professionals who are owners or employees of the group practice; prescribing health care professional shall mean a physician or other

health care professional licensed to prescribe drugs in the State in which the drugs are dispensed; PDP sponsor or MA organization shall have the meanings set forth at §§ 423.4 and 422.2, respectively.

Dated: March 15, 2005.

Daniel R. Levinson,
Acting Inspector General.

Approved: August 12, 2005.

Michael O. Leavitt,
Secretary.

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