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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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[CMS-1303-F]

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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: Final rule.

SUMMARY: As required by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), this final rule creates 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 compensation in the form of items or services (not including cash or cash equivalents) ("nonmonetary remuneration") that is necessary and used solely to receive and transmit electronic prescription information. In addition, using our separate legal authority under section 1877(b)(4) of the Act, this rule creates a separate regulatory exception for certain arrangements involving the provision of nonmonetary remuneration in the form of electronic health records software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records. These exceptions are consistent with the President's goal of achieving widespread adoption of interoperable electronic health records to improve the quality and efficiency of health care while maintaining the levels of security and privacy that consumers expect.

DATES: *Effective date:* These regulations are effective on October 10, 2006.

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SUPPLEMENTARY INFORMATION:

I. Background

This final rule establishes exceptions to the physician self-referral law for certain arrangements involving the donation of electronic prescribing and electronic health records technology and training services. Set forth below is

a brief background discussion addressing:

- The physician self-referral law and its exceptions;
- A summary of the relevant provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), (Pub. L. 108-173);
- The Secretary's authority to implement exceptions under section 1877(b)(4) of the Social Security Act (the Act); and
- The November 9, 2005 Open Door Forum on electronic prescribing and electronic health records.

A. The Physician Self-Referral Law and Exceptions

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 or billing the beneficiary or third party payor 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.

B. Section 101 of the MMA

Section 101 of the MMA added a new section 1860D to the Act establishing a prescription drug benefit in the Medicare program. As part of the new statutory provision, in section 1860D-4(e)(4) of the Act, the Congress directed the Secretary 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. (See 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 that would protect certain arrangements involving the provision of compensation in the form of nonmonetary 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 information in accordance with electronic prescribing standards published by the Secretary under section 1860D-4(e)(4) of the Act.

Specifically, this new exception sets forth conditions under which the provision of such remuneration by hospitals, group practices, and prescription drug plan (PDP) sponsors and Medicare Advantage (MA) organizations (collectively, for purposes of this preamble discussion, donors) to prescribing physicians (collectively, for purposes of this preamble discussion, physician recipients) would be protected. As we noted in the preamble to the October 11, 2005 proposed rule, depending on the circumstances, provisions in the existing physician self-referral regulations may also provide protection for the donation of these items and services to physicians.

In addition to mandating the new exception to the physician self-referral prohibition, section 1860D-4(e)(6) of the Act directs the Secretary to create a corresponding safe harbor under the anti-kickback statute (section 1128B(b) of the Act, 42 U.S.C. 1320a-7b(b)). The Health and Human Services Office of Inspector General (OIG), the agency that enforces the anti-kickback statute, is promulgating that safe harbor through a separate rulemaking. We have attempted to ensure as much consistency as possible between our final electronic prescribing exception and the corresponding final safe harbor, given the differences in the respective underlying statutes. One significant difference in the statutory schemes is that complying with a safe harbor under the anti-kickback statute is voluntary, whereas fitting in an exception under section 1877 of the Act is mandatory. In other words, arrangements that do not comply with a safe harbor may not necessarily violate the anti-kickback statute. Rather, such arrangements are subject to the customary case-by-case review under the statute. If an arrangement fails to meet all requirements of a physician self-referral exception, however, it violates section 1877 of the Act. Another difference is that section 1877 of the Act applies only to referrals from physicians, while the anti-kickback statute applies more broadly.

C. Section 1877(b)(4) Authority

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 final rule also sets forth terms and conditions for a separate exception to the physician self-referral prohibition for certain arrangements involving the donation of electronic health records software or information technology and training

services. Information technology, and electronic health records in particular, supports treatment choices for consumers and enables better and more efficient care, while maintaining the levels of security and privacy that consumers expect. We seek to encourage the adoption of such technology through this final rulemaking. We believe that electronic health records systems that are secure and interoperable may mitigate many of our concerns regarding the potential anticompetitive effects of stand-alone electronic health records systems.

D. Open Door Forum

We held an Open Door Forum early in the comment period for the proposed rule, on November 9, 2005, to discuss the benefits and risks of donating electronic prescribing and electronic health records technology. The OIG also participated in this Open Door Forum. This Open Door Forum was in addition to, and not in lieu of, the public comment process. During this Open Door Forum, panelists representing the health care industry (for example, the American Hospital Association and the American College of Physicians), the health information technology industry, and members of the public contributed to the discussion. Panelists described the types of technology they believe are necessary to have a useful, workable, interoperable electronic health records system, including software, training, connectivity, upgrades, and a help desk function. The following topics were also included in the discussion:

- The cost of the technology to the donor versus the value to the physician and a cap on the value of the technology;
- Safeguards necessary to protect against program or patient abuse, including permissible donors and recipients and donation selection criteria;

- Staged implementation;
- Standards for the certification of the technology;
- Physician certification of technical and functional equivalence; and
- The limitations of electronic prescribing functionality alone as opposed to electronic prescribing functionality integrated into electronic health records software.

II. Provisions of the October 11, 2005 Proposed Rule

On October 11, 2005, we published a proposed rule to issue three exceptions under the physician self-referral statute (70 FR 59182). The first proposed exception addressed arrangements involving electronic prescribing technology as required by section 101 of the MMA. Many industry and government stakeholders had expressed concerns that the MMA provision was not sufficiently useful or practical, and would not adequately advance the goal of achieving improved health care quality and efficiency through widespread adoption of interoperable electronic health records systems. Accordingly, we proposed two additional exceptions to address donations of certain electronic health records software and directly related training services, using our authority at section 1877(b)(4) of the Act. One proposed exception would have protected certain arrangements involving nonmonetary remuneration in the form of interoperable electronic health records software certified in accordance with criteria adopted by the Secretary (and directly related training services). The second proposed exception would have protected certain arrangements involving donations of electronic health records technology made before the adoption of certification criteria. The proposed rule for safe harbors under the anti-kickback

statute, issued the same day, contained comparable proposals.

In response to our proposed rule, we received 74 timely filed comment letters. The majority of the comments came from hospitals and health systems, trade associations, and vendors. We also received comments from information technology organizations, health plans, and providers.

The OIG received 71 timely filed comment letters. The majority of the comments came from the same types of entities from which CMS received its comments. However, the OIG also received comments from pharmaceutical manufacturers and pharmacies.

Overall, the commenters welcomed the establishment of exceptions and safe harbors for electronic prescribing and electronic health records technology arrangements. However, we received many specific comments about various aspects of the proposed rule.

After considering these public comments, we are finalizing two exceptions:

- An exception that protects certain arrangements involving electronic prescribing technology (new § 411.357(v)); and
- An exception that protects certain arrangements involving interoperable electronic health records software or information technology and training services (new § 411.357(w)).

These final exceptions create separate and independent grounds for protection under the physician self-referral law. For the convenience of the public, we are providing Chart 1 that lays out schematically the overall structure and approach of the final exceptions, details of which we are providing in sections III and IV of this preamble. Readers are cautioned that the final exceptions contain additional conditions and information not summarized in Chart 1.

CHART 1.

	MMA-mandated electronic prescribing exception § 411.357(v)	Electronic health records exception § 411.357(w)
Authority for Exception	Section 101 of the MMA	Section 1877(b)(4) of the Social Security Act.
Covered Technology	Items and services that are necessary and used solely to transmit and receive electronic prescription information.	Software necessary and used predominantly to create, maintain, transmit, or receive electronic health records. Software packages may include functions related to patient administration, for example, scheduling functions, billing, and clinical support.
	Includes hardware, software, internet connectivity, and training and support services.	Software must include electronic prescribing capability.

CHART 1.—Continued

	MMA-mandated electronic prescribing exception § 411.357(v)	Electronic health records exception § 411.357(w)
Standards with Which Donated Technology Must Comply.	Applicable standards for electronic prescribing under Part D (currently, the first set of these standards is codified at § 423.160).	Information technology and training services, which would include, for example, internet connectivity and help desk support services. Electronic prescribing capability must comply with the applicable standards for electronic prescribing under Part D (currently, the first set of these standards is codified at § 423.160). Electronic health records software must be interoperable. Software may be deemed interoperable under certain circumstances.
Donors and Recipients	As required by statute, protected donors and recipients are hospitals to members of their medical staffs; group practices to physician members; PDP sponsors and MA organizations to prescribing physicians.	Entities that furnish designated health services (DHS) to any physician.
Selection of Recipients	Donors may not take into account directly or indirectly the volume or value of referrals from the recipient or other business generated between the parties.	Donors may use selection criteria that are not directly related to the volume or value of referrals from the recipient or other business generated between the parties.
Value of Protected Technology	No limit on the value of donations of electronic prescribing technology.	Physician recipients must pay 15 percent of the donor's cost for the donated technology and training services. The donor may not finance the physician recipient's payment or loan funds to the physician recipient for use by the physician recipient to pay for the items and services.
Expiration of the Exception	None	Exception sunsets on December 31, 2013.

General Comments and Responses to the Proposed Rule

Comment: Most commenters supported the promulgation of exceptions for electronic prescribing and electronic health records arrangements. Commenters observed that both the Congress and the Administration have recognized the compelling need for rapid and widespread adoption of electronic prescribing and electronic health records technology. Several commenters suggested that fraud and abuse concerns should not impede the adoption of health information technology. In this regard, commenters suggested that the final rule should better balance the goal of preventing fraud and abuse with the goal of creating incentives for health information technology arrangements that reduce fraud and abuse, increase quality and efficiency, and improve patient care. One commenter asserted that investments in health information technology and the desire to provide an incentive to participate in health information technology systems do not raise typical fraud and abuse concerns present with other financial arrangements. However, another commenter noted that the proposed rule generally struck an appropriate balance between the needs of physicians who

may require assistance to develop health information technology systems and the underlying purpose of Federal fraud and abuse laws to promote the professional independence of the physicians receiving the support.

Response: We disagree with the commenter that suggested that financial arrangements involving incentives in the form of health information technology do not pose the same fraud and abuse concerns as other financial arrangements between parties in a potential referral relationship. Indeed, our enforcement experience demonstrates that improper remuneration for Medicare referrals may take many forms, including free computers, facsimile machines, software, and other goods and services. However, we recognize that certain arrangements for the transfer of health information technology between parties with actual or potential referral relationships may further the important national policy of promoting widespread adoption of health information technology to improve patient safety, quality of care, and efficiency in the delivery of health care. We believe the final rule strikes the appropriate balance between promoting the adoption of health information

technology and protecting against program or patient abuse.

Comment: Several commenters stated that the Congress and the Administration need to offer meaningful financial incentives for practitioners to accept the increased cost and workflow burdens associated with the implementation of health information technology. For example, the government could provide modest add-on payments to physicians who employ health information technology as part of overall quality improvement measures. Some commenters observed that the proposed rule would remove a minor impediment to the adoption of health information technology, but suggested that we must play a larger role in providing capital for the technologies that assist physicians in providing quality care and avoiding medical errors.

Response: These comments address matters outside the scope of this rulemaking. However, we note that the Administration supports the adoption of health information technology as a normal cost of doing business. Specifically, the 2007 Budget states that “[t]he Administration supports the adoption of health information technology (IT) as a normal cost of

doing business to ensure patients receive high quality care.”

Comment: Some commenters complained that the proposed exceptions were too narrow and vague. These commenters urged that the final exceptions should be easy to understand, interpret, and enforce so that donors and physicians readily can distinguish permissible activities from those that violate the statute. Some commenters believe that the proposed rule was too complex and might have the unintended effect of discouraging participation in health information technology arrangements.

Response: As described in this preamble, we have adopted a number of modifications and changes that address the commenters' concerns. Although the final exception at § 411.357(v) addresses only electronic prescribing arrangements, the final exception at § 411.357(w) protects a broad scope of arrangements involving electronic health records technology. We have made a number of changes that clarify and simplify the final rules. We have endeavored to create bright line provisions to the extent possible. Moreover, we do not believe that the Congress, in enacting section 1860D-4(e)(6) of the Act, intended to suggest that a new exception is needed for all arrangements involving the provision of electronic prescribing items and services, nor do we believe that an exception is needed for all electronic health records arrangements. Many arrangements can be structured to fit in existing exceptions.

Comment: Some commenters observed that the description of the nonmonetary remuneration that would be included in the exceptions as proposed did not reflect the many existing combinations and varieties of electronic prescribing, electronic health records, and similar technology.

Response: As discussed in greater detail, we believe that the final exceptions are sufficiently broad to accommodate the most essential current and evolving electronic prescribing and electronic health records technology. We began this rulemaking process by looking to the guidance from the Congress in section 101 of the MMA with respect to electronic prescribing technology. Using our regulatory authority, we have added a separate exception for arrangements involving electronic health records software or information technology and training services. We believe that we have appropriately balanced the goal of promoting widespread adoption of health information technology against the significant fraud and abuse concerns

that stem from the provision of free or reduced cost goods or services to actual or potential referral sources.

Comment: A commenter suggested that the final rule should include provisions that allow us to evaluate and ensure that the regulatory requirements, once enacted, have not negatively impacted key stakeholders or business segments within the health care industry.

Response: Nothing in this rulemaking prevents us from reviewing the impact of the regulations on stakeholders in the health care industry. As with all regulatory exceptions, we may, in future rulemaking, propose modifications or clarifications to the exception as appropriate.

Comment: We solicited comments on whether and, if so, how to take into account physician access to publicly available software at free or reduced prices. One commenter urged that the availability of free public software should not impact the design of the final exceptions. In addition, the commenter stated that we should grant physicians and hospitals substantial latitude in selecting interoperable technology that best meets their needs.

Response: After further consideration, we concluded that it was not necessary to take the availability of publicly available software into account in developing the final exceptions. Hospitals, physicians, and other donors will have great flexibility in selecting technology that will qualify for protection under the exceptions. Nothing in this rule limits the choice of health information technology, although certain technology, such as non-interoperable electronic health records software (as discussed in section IV), would not qualify for protection because it would not meet all of the conditions of the exception.

Comment: Some commenters suggested that the exceptions under the physician self-referral law should mirror the safe harbors under the anti-kickback statute in all respects in order to promote the rapid and widespread adoption of electronic prescribing and electronic health records technology. A few commenters suggested that OIG not adopt anti-kickback statute safe harbors or that any safe harbors should be stricter than any corresponding exceptions to the physician self-referral law.

Response: We believe consistency between these exceptions and the corresponding safe harbors under the anti-kickback statute is preferable. We have attempted to ensure as much consistency between the two sets of regulations as possible given the

underlying differences in the two statutory schemes.

Comment: A few commenters requested that the Federal physician self-referral exception preempt State laws that prohibit physician self-referrals relating to health information technology. One commenter wanted the physician self-referral exceptions, once finalized, to preempt any State laws or regulations that conflict with the provisions of the exceptions.

Response: The MMA specifically dictated that the Part D electronic prescribing standards would preempt any State law or regulation that—(1) Is contrary to the adopted final Part D electronic prescribing standards or that restricts the Secretary's ability to carry out Part D of title XVIII; and (2) pertains to the electronic transmission of medication history and of information on eligibility benefits, and prescriptions with respect to covered Part D drugs under Part D. No similar authority was provided with respect to the physician self-referral exception for the donation of electronic prescribing technology. Moreover, the legal authority for the electronic health records exception in this rule is derived from section 1877(b)(4) of the Act, which similarly does not provide authority to preempt State physician self-referral laws. Existing Federal physician self-referral law permits States to regulate physician self-referrals concurrently.

Comment: Some commenters inquired whether the electronic information that is transmitted via electronic prescribing or electronic health records systems would be considered remuneration for purposes of the physician self-referral law.

Response: Whether a particular item or service constitutes remuneration for purposes of the physician self-referral law depends on the particular facts and circumstances. Typically, information about a particular patient's health status, medical condition, or treatment exchanged between or among the patient's health care providers and suppliers for the purpose of diagnosing or treating the patient would not constitute remuneration to the recipient of the information. In this regard, the electronic exchange of patient health care information is comparable to the exchange of such information by mail, courier, or phone conversation. Thus, when related to the care of individual patients, information such as test results, diagnosis codes, descriptions of symptoms, medical history, and prescription information are part of the delivery of the health care services and would not have independent value to the recipient. However, in other

situations, information may be a commodity with value that could be conferred to induce or reward referrals. For example, data related to research or marketing purposes, or information otherwise obtained through a subscription or for a fee, could constitute remuneration for purposes of the physician self-referral law.

III. Response to Comments and Final Rule Provisions Regarding Electronic Prescribing Exception Required Under Section 101 of the MMA (proposed § 411.357(v))

A. Summary of the Proposed Provisions Related to § 411.357(v)

On October 11, 2005, as mandated in the MMA, we proposed adding a new paragraph (v) to the existing regulations at § 411.357 for certain electronic prescribing arrangements. We proposed the following:

- That the exception would protect certain arrangements involving the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information. We construed this language broadly to include internet connectivity services (of all types, including broadband or wireless), and upgrades of equipment and software that significantly enhance functionality.
- That the donated technology must be part of, or used to access, a prescription drug program that meets applicable standards under Medicare Part D.
- That the technology must be donated by a hospital to members of its medical staff, by a group practice to its members, or by a PDP sponsor or MA organization to prescribing physicians, as long as all of the exception conditions are satisfied.
- That the physician could not make the receipt of donated technology a condition of doing business with a donor.
- That protected arrangements must be fully and completely documented.
- That the exception would not protect donations of technology that replicate technology the physician already possessed. To ensure compliance with this provision, we proposed requiring physicians to certify that they did not already possess equivalent technology. Moreover, we proposed that donors would not be protected if they knew or should have known that the physicians already possessed equivalent technology.
- That neither a physician's eligibility for donated technology, nor the amount

or nature of the technology, could be determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

- That the parties could not take any action to impede the compatibility or interoperability of the technology.
- That the donor could not restrict the ability of the physician to use the technology for any patient, regardless of payor.
- Limiting the value of donated technology that could be protected by the exception.
- A separate exception for multifunctional items and services used for electronic prescribing (for example, multi-use hand-held devices) because we recognized the limitations imposed by the "used solely" standard set forth in the MMA.

B. General Comments

Comment: Many commenters stated that the proposed electronic prescribing exception was too narrow to be useful and should be merged into an electronic health records exception, noting that physicians would likely resist adopting stand-alone electronic prescribing systems. One commenter observed that the proposed rule was generally in accordance with the congressional intent underlying section 101 of the MMA.

Response: We agree that the proposed exception was consistent with congressional intent. As we are not free to ignore a congressional mandate, we must promulgate the electronic prescribing exception described in section 101 of the MMA. However, we are also promulgating a separate exception for electronic health records arrangements that incorporate an electronic prescribing component. This new exception should address the commenters' concerns.

C. Specific Comments

1. Protected Compensation in the Form of Items and Services (Nonmonetary Remuneration)

The proposed rule clarified the items and services that would qualify for the new exception (for purposes of this preamble, "qualifying electronic prescribing technology") that the Congress authorized only for the provision of items and services that are "necessary and used solely" to transmit and receive electronic prescription drug information.

a. Covered Technology

In our proposed exception, we proposed protecting hardware, software,

or information technology and training services that met the various exception conditions. We interpreted the statutory language to include the donation of 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.

Comment: Various commenters suggested that the scope of covered technology should be expanded to include: billing, scheduling, and other administrative functions; implementation and maintenance of the system; upgrades; and licenses, rights of use, or intellectual property. Commenters also urged that any exception cover educational sessions and consulting assistance related to the electronic prescribing technology. Commenters generally agreed that the provision of equipment for personal, non-medical purposes should not be protected. One commenter suggested that it would not be possible to develop a comprehensive list of protected remuneration that would sufficiently reflect all possible electronic prescribing items and services. The commenter recommended that we periodically review the scope of protected items and services, and expand it as needed.

Response: We agree that it would be difficult to provide a comprehensive list of items and services covered by the exception. Although a specific list would provide a "bright line" rule, in this case, it would also impede the ability of the exception to accommodate novel or rapidly evolving technologies in the marketplace. For these reasons, we are not promulgating a specific list of protected items and services.

Consistent with the MMA mandate, covered items and services under § 411.357(v) include "hardware, software, and information technology and training services" that are necessary and used solely for electronic prescribing and that meet the other conditions of the exception. We believe that licenses, rights of use, intellectual property, upgrades, and educational and support services (including, for example, help desk and maintenance services) are items and services that potentially can fit in the exception if all conditions of the exception are met. Billing, scheduling, administrative, and other general office software cannot. Operating software that is necessary for the hardware to function can qualify for protection under the exception because it is integral to the hardware and distinct from other software applications that are not necessary to transmit and receive electronic

prescribing information. Interfaces designed to link the donor's existing electronic prescribing system to the physician's existing electronic prescribing system can qualify for protection. The exception does not protect the provision of technology for personal, nonmedical purposes, nor does the exception protect the provision of office staff.

Comment: We solicited comments on whether the exception should protect electronic prescribing technology that is used for the transmission of prescription information for items and services that are not drugs (for example, durable medical equipment (DME) or laboratory tests). Several commenters suggested that the exception should support the use of electronic prescribing technology for all the functions currently accomplished through written prescriptions, in order to encourage provider utilization of electronic prescribing technology to increase safety, cost-effectiveness, and efficiency. The commenters suggested including the use of electronic prescribing technology used for prescribing medical supplies and durable medical equipment, physical therapy, dialysis testing, laboratory tests, and other nondrug prescriptions. A commenter from the clinical laboratory industry supported a broad reach, but only if clinical laboratories were included as permissible donors under the exception.

Response: We agree generally with the first set of commenters. We have reviewed further the language in section 101 of the MMA. The exception mandated by section 1860D-4(e)(6) of the Act requires that the donated technology be capable of receiving and transmitting "electronic prescription information" in accordance with the electronic prescribing standards promulgated for purposes of the MMA electronic prescription drug programs described in section 1860D-4(e)(1) through (3) of the Act. We believe that the specific term electronic "prescription information" as commonly used and as used in section 1860D-4(e)(6) of the Act retains a broad meaning, to include information about prescriptions for any items that would normally be conducted with a written prescription. In contrast, the information to be transmitted under an electronic prescription drug program established under section 1860D-4(e)(2) of the Act is clearly limited to drug information for Part D eligible individuals. Moreover, we do not believe that the statutory language is intended to be construed to prohibit the use of the donated technology for the transmission and receipt of orders or

prescriptions for other items and services or to require the use of separate systems depending on the payor or the item or service to be prescribed or ordered. We believe this approach is consistent with the broad applicability of the physician self-referral law, the objectives of the electronic prescribing standards, and the patient safety, quality, and efficiency goals underlying the mandated exception. Accordingly, we are defining "prescription information" for purposes of the exception to mean information about prescriptions for drugs or any other item or service normally accomplished through a written prescription. With respect to the clinical laboratory commenter, consistent with the MMA language, we are not including clinical laboratories as permissible donors under the exception. However, we have expanded the new exception for electronic health records arrangements to include clinical laboratories.

b. "Necessary and Used Solely"

In the proposed rule, we proposed protecting items and services that are necessary and used solely to transmit and receive electronic prescription information. We stated that the exception would not protect arrangements in which donors provide items or services that are technically or functionally equivalent to items that the receiving physician already possessed or services that the physician had already obtained. We proposed requiring the physician to certify that the items and services provided were not technically or functionally equivalent to those that the physician already possessed or had already obtained. We also proposed that arrangements would not be protected if the donor knowingly provided technology that duplicated the physician's existing technology. We indicated that we would consider "necessary," for purposes of the exception, upgrades of equipment or software that significantly enhance the functionality of the item or service.

Because the term "necessary" appeared in our proposed rule in the discussions of all three proposed exceptions, many commenters chose to address comments on the meaning of the term "necessary" in the context of the proposed exceptions for electronic health records arrangements. We intend to interpret the term "necessary" uniformly for both new exceptions. Thus, there is a detailed discussion of our interpretation of the term "necessary" in section IV.C of this preamble, which addresses the new electronic health records exception. We

are addressing here only the comments received on the "necessary and used solely" requirement that are specific to the proposed electronic prescribing exception.

Comment: One commenter observed that the "necessary and used solely" requirement ensures that items and services will be used to encourage electronic prescribing activities. This commenter suggested including an additional requirement that the items or services clearly be intended to promote the interoperability of health information technology and the improvement of quality in a clinical setting.

Response: We agree that it was the intent of the Congress to encourage electronic prescribing activities, in part, through the development of an exception for donations of certain items and services necessary and used solely for electronic prescribing transactions. However, the additional standards suggested by the commenter, while reflecting laudable goals, are not sufficiently "bright line" for purposes of this exception. We have included a requirement at § 411.357(v)(3) intended to ensure that protected technology meets Part D electronic prescribing standards applicable at the time of the donation, including any standards relating to interoperability.

Comment: Some commenters expressed concern that we have taken an unnecessarily narrow interpretation of the statutory language "necessary and used solely to receive and transmit electronic prescription information in accordance with the standards promulgated under [section 101 of the MMA]." One commenter explained its view that the phrase "necessary and used solely" should be read such that the word "necessary" modifies the phrase "in accordance with the standards issued under this subsection." In other words, in this commenter's view, the protected hardware, software, and services must be "necessary" to perform electronic prescribing transactions "solely" in accordance with CMS-established data interchange standards. The commenter explained that this interpretation would be consistent with the purpose of the exception and the practical realities of computers and electronic transactions.

Response: We appreciate the comment; however, we do not believe that the commenter's proposed interpretation is the best or most logical reading of the statutory language. We believe the better and less strained reading is that the Congress intended for all donated technology to be necessary for the receipt and transmission of

electronic prescription information and to be used solely for that purpose. Limiting the exception to necessary items and services helps ensure that the exception does not become a means of conveying valuable items and services that do not further the underlying policy goals and that might, in reality, constitute disguised payments for referrals. As we noted in the preamble to the proposed rule, we believe that the Congress included the “used solely” requirement to safeguard against abusive arrangements in which the donated 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. Accordingly, consistent with section 101 of the MMA, the final exception requires that the protected items and services be necessary and used solely to receive and transmit electronic prescribing information.

We note that software that bundles general office management, billing, scheduling, electronic health records, or other functions with the electronic prescribing features does not meet the “used solely” requirement and is not protected by the final electronic prescribing exception. In some cases, the provision of such bundled software may be eligible for protection under the new exception for electronic health records arrangements at § 411.357(w).

Comment: One commenter suggested that the definition of “necessary” include all components required for a physician to be enabled to prescribe electronically whether or not other functionality is available or incorporated into the electronic prescribing technology.

Response: We believe that the commenter is referring to technology that is beyond the scope of the MMA-mandated exception. We have elected not to finalize a multifunctional electronic prescribing exception. The final exception for arrangements involving the donation of electronic health records technology may address the commenter’s concerns.

Comment: Many commenters requested that we eliminate the proposed requirement that physicians provide written certification that the donated technology is not technically or functionally equivalent to the technology that the physician already possesses. Several commenters expressed concern about the potential difficulty of making this determination,

the potential lack of expertise on the part of some physicians, and the potential increased cost that could arise by having an outside expert provide a determination of technical or functional equivalence.

Response: For the reasons noted in section IV of this preamble with respect to the electronic health records exception, we are not adopting the proposed requirement that physicians provide written certification that the donated technology is not technically or functionally equivalent to technology the physician already possesses. Although we have eliminated the certification requirement, we retained the requirement for written documentation regarding the specifics of the arrangement in the final exception at § 411.357(v)(7).

We do not believe that items and services are “necessary” if the physician already possesses equivalent items and services. The provision of duplicative items and services poses a heightened risk of abuse, since such arrangements would confer independent value on the physician (that is, the value of the existing items and services that may be put to other uses) unrelated to the need for electronic prescribing technology. Thus, if a donor knows that the physician already possesses equivalent items or services, or acts in deliberate ignorance or reckless disregard of that fact, the exception will not protect the donation. Therefore, prudent donors may want to make any reasonable inquiries to potential physician recipients and document the communications. We do not believe this requirement necessitates the hiring of technical experts by either the donor or the physician recipient.

Comment: One commenter supported our interpretation of the term “necessary” as permitting upgrades of equipment or software that significantly enhance the functionality of an item or service. Another commenter suggested that we should not require that the upgrades “significantly” enhance the functionality of the item or service. Rather, the commenter believes that we should allow the marketplace to determine whether an upgrade constitutes a beneficial improvement.

Response: Although we continue to believe that the term “necessary” does not preclude upgrades of equipment or software that significantly enhance the functionality of the item or service, we agree with the commenter that distinguishing “significant” enhancements from other beneficial improvements introduces unnecessary complexity. Under the final exception, any upgrade that is necessary and used

solely to transmit and receive electronic prescribing information is protected (as long as all other conditions of the exception are satisfied).

Comment: Many commenters noted that it would be impractical to require physicians to acquire or use software and hardware solely for electronic prescribing. Several commenters noted that, in most cases, single-use technology is of limited value to a physician, and could result in inefficiencies. Another commenter expressed concern that the “used solely” standard would preclude the use of robust electronic clinical support tools, such as tools to identify drug-to-drug interactions or to conduct drug-to-lab or prescription data analysis. This commenter urged that any exceptions from the physician self-referral prohibition for health information technology arrangements promote access to all information needed by physicians to evaluate alternative drug therapies, identify potential drug-to-drug interactions, and to improve safety, quality, and efficiency of patient care.

Response: The “used solely” condition derives directly from the MMA language. We believe that many of the arrangements of interest to the commenters are addressed best by the electronic health records exception, which is not restricted to technology used solely for electronic prescribing. The MMA-mandated electronic prescribing exception reasonably is interpreted to encompass electronic tools that provide information necessary to formulate, transmit and receive a medically appropriate prescription for a patient. These tools would include electronic clinical support tools identifying alternative drug therapies, drug-to-drug interactions, or a payor’s formulary information.

The nature of the “prescription data analysis” tools referenced by the commenter is not clear. We believe the appropriate inquiry would be whether the tool is used to formulate, transmit and receive a medically appropriate prescription for a patient. To the extent the data analysis tool (or any other electronic item or service) is used to transmit and receive data unrelated to formulating a medically appropriate prescription for a patient (for example, data collected for marketing purposes), the tool would not be necessary for electronic prescribing and would not be protected under the exception.

c. Standards

The MMA required that donated electronic prescribing technology must comply with the standards for electronic prescribing under Medicare Part D at the

time the items and services are donated. In the November 7, 2005 **Federal Register** (70 FR 67568), we finalized the first set of these standards (the “foundation standards”). We proposed in § 411.357(v)(2) a requirement that the items and services be provided as part of, or be used to access, an electronic prescription drug program that complies with the applicable standards under Medicare Part D at the time the items and services are donated.

We received no comments on this issue. The final exception requires that the donated technology must comply with the applicable standards under Medicare Part D at the time the items and services are donated.

2. Permissible Donors and Physician Recipients

We proposed protecting the same categories of donors and physician recipients listed in section 101 of the MMA.

Comment: We received numerous comments requesting that we expand the list of permissible donors and physician recipients.

Response: Because most commenters commented on this issue jointly with the proposed electronic health records exception, we included a detailed discussion of these comments in our discussion of the electronic health records exception in section IV.D. of this preamble.

We are finalizing the exception consistent with the MMA-mandated donors and physician recipients set forth by the Congress. We are not persuaded that additional donors or physicians are necessary to achieve the purpose of this exception for electronic prescribing. The enumerated categories of donors and physicians reflect individuals and entities centrally involved in the ordering, processing, filling, or reimbursing of prescriptions. Accordingly, protected donors and physicians under § 411.357(v) are hospitals to members of their medical staffs, group practices to their physician members, and PDP sponsors and MA organizations to prescribing physicians. For the convenience of the reader, we note the following:

- *Group practice* is defined as specified in § 411.352;
- *Members of a group practice* is defined as all persons covered by the definition of “member of a group practice” at § 411.351;
- *PDP sponsor* or *MA organization* is defined as specified in § 423.4 and § 422.2, respectively.

3. Selection of Physician Recipients

We proposed additional conditions in proposed §§ 411.357(v)(5) and (v)(6) related to how donors select recipients of the electronic prescribing technology. These proposed conditions were designed to minimize the risk that donors would select recipients for the improper purpose of inducing or rewarding the generation of Medicare business. Proposed § 411.357(v)(5) would require that the recipients (including their groups, employees, or staff) refrain from making the donation of qualifying electronic prescribing technology a condition of doing business with the donor. Proposed § 411.357(v)(6) would preclude protection if the eligibility of a physician to receive items and services from a donor, or the amount or nature of the items or services received, is determined in any manner that takes into account the volume or value of the physician’s referrals or other business generated between the parties. We observed that this requirement would not preclude selecting a recipient based upon the total number of prescriptions written by the recipient, but would preclude selecting the recipient based upon the number or value of prescriptions written by the recipient that are dispensed or paid by the donor (as well as on any other criteria based on any other business generated between the parties). (see October 11, 2005 proposed rule, (70 FR at 59187)).

Comment: Commenters requested that we confirm that donors can select physician recipients of electronic prescribing technology based upon the total number of prescriptions written by the physician, but cannot select them based upon the number or value of prescriptions written by the physician recipient that are dispensed or paid by the donor (or on any other criteria based on any other business generated between the parties). A commenter supported excluding from the protection of the exception donations that take into account *directly* the volume or value of referrals or other business generated between the parties. This commenter expressed concern that donors would employ such selection criteria to disadvantage small practices and practices in rural or underserved areas. To counter this potential disadvantage, the commenter suggested that the final rule include incentives to promote donations to small practices, especially in rural and underserved areas. Other commenters suggested that donors, such as PDP sponsors and MA organizations should be permitted to consider the volume and value of prescriptions

written by the physician recipient, particularly for a donor’s patient or plan population.

Response: To safeguard against the use of donated technology to disguise referral payments, we are adopting our proposal that neither the eligibility of a physician to receive items and services, nor the amount or nature of the items or services received, may be determined in a manner that takes into account, directly or indirectly, the volume or value of the physician’s referrals or other business generated between the parties. Notwithstanding, in the instant case, we believe that prohibiting the selection of recipients based on total number of prescriptions written by the recipient would be inconsistent with the MMA mandate and congressional intent to promote the use of electronic prescribing. Accordingly, we confirm our interpretation, for purposes of the exception at § 411.357(v), that donors may select physician recipients of electronic prescribing technology based upon the total number of prescriptions written by the physician, but cannot select them based upon the number or value of prescriptions written by the physician that are dispensed or paid by the donor (or on any other criteria based on any other business generated between the parties). They also may not select physician recipients based on the overall value of prescriptions written by the physician or on the volume or value of prescriptions written by the physician that are reimbursable by the Medicare program.

We are not persuaded that PDP sponsors or MA organizations should be permitted to offer technology selectively based on the volume or value of business generated for the plan by the recipient, especially in the context of Part D, which includes some reimbursement based on the plan’s costs, rather than capitated payments.

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), because such arrangements take into account business generated for the donor. We understand the commenter’s concern about donors excluding rural and underserved area physicians from their health information technology arrangements. Some donors may favor large or urban practices over small or rural ones. However, we can discern no “incentives” that could be included appropriately in an exception to address

this concern, nor has the commenter proposed any with respect to assisting rural or solo practitioners. We note that our decision not to limit the value of technology that can qualify under the exception may assist rural and solo practices insofar as donors may want to provide them with greater resources in recognition of their greater need for assistance in adopting electronic prescribing technology.

Comment: Some commenters supported our proposal to exclude from the protection of the exception donations that are a condition of doing business with the donor.

Response: We are retaining the proposed requirement that recipients (or any affiliated group, employee, or staff member) cannot make the receipt of items or services a condition of doing business with the donor. We have clarified that the condition applies with respect to all individuals and entities affiliated with the recipient.

4. Value of Technology: Cap

In our proposed rule, we solicited public comments on various means by which we might limit the value of protected technology under the electronic prescribing exception. We indicated that we were considering a limit on the value of protected technology as a further safeguard against program or patient abuse. We received a large number of comments on this topic, the majority of which opposed any limit on the value of donated technology. Because these commenters typically commented jointly on this issue for all three proposed exceptions (and each commenter typically had the same concerns under all three proposed exceptions), an extensive description of these comments is found in section IV of this preamble. Having considered the comments, we are persuaded not to limit the value of the donated technology under the new exception for electronic prescribing arrangements at § 411.357(v). We believe the final conditions of the exception, including the “necessary and used solely” requirement and the conditions related to how donors select physician recipients, should be sufficient to guard against program and patient abuse. Although we are not limiting the value of donated technology, it is not our expectation that donors will necessarily want, or be in a position, to donate unlimited amounts of electronic prescribing technology.

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

a. All Payors Requirement

In proposed § 411.357(v)(4), we stated that we would require that, where possible, physicians must be able to use the protected technology for all patients without regard to payor status.

Comment: Commenters universally supported the requirement that, where possible, physicians must be able to use the donated technology for all patients regardless of payor source.

Response: We agree, and we have included this requirement in the final exception.

b. Documentation

We proposed at § 411.357(v)(7) a requirement that the arrangement for the donation of electronic prescribing technology be in writing, be signed by the parties, identify with specificity the items or services being provided and their values, and include a certification that the donated items and services are not technically or functionally equivalent to items and services the physician recipient already has. We stated that, to permit effective oversight of protected arrangements, the writing must cover all qualifying electronic prescribing technology provided by the donor to the physician. 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).

Comment: Some commenters supported the requirement that any transfers of technology and services be memorialized in a written agreement. One commenter objected to including a written agreement requirement in the exception, arguing that the requirement would cause an unnecessary delay and increase paperwork. Another commenter suggested that the exception permit the arrangement between the donor and physician recipient to be captured through a combination of agreements between the recipient, donor, and service provider, rather than one agreement. Commenters also urged us to remove the technical and functional equivalence certification requirement from the exception.

Response: We have adopted a documentation requirement in the exception at § 411.357(v)(7) with several modifications. With respect to the condition requiring that the documentation cover all of the

electronic prescribing items and services provided by the donor to the physician recipient, we have added language to the final exception clarifying that the written documentation requirement can be satisfied by incorporating by reference other agreements between the parties or by the use of cross references to a master list of agreements between the parties that is maintained and updated centrally, is available for review by the Secretary upon request, and preserves the historical record of agreements. We have eliminated the certification of technical and functional non-equivalence. In addition, given our decision not to limit the value of protected donations, we have eliminated the requirement that the agreement specify the value of the donated technology. However, in the interests of transparency and accountability, we are requiring that the parties document the donor’s cost for the technology. We have retained the remaining documentation requirements, as proposed, at § 411.357(v)(7).

c. Commercial and Other Messaging

Comment: A commenter requested clear and specific rules prohibiting inappropriate commercial messaging through electronic prescribing technology, including electronic detailing messages from a manufacturer promoting a particular brand or brand-name drug. This commenter suggested that such messaging may inappropriately influence clinical decision-making. The commenter gave the following as examples of inappropriate messaging: (1) Messages disguised as “clinical alerts” based upon biased research not published in the public domain; and (2) alerts purporting to save a patient money when, in reality, the out-of-pocket expense for the drug to the patient is higher. Another commenter suggested that we should prohibit commercial messaging and require that donated technologies present information in a neutral and transparent manner so as not to influence clinical decision making improperly. Similarly, another commenter noted that pop-up messaging could influence inappropriately prescribing patterns. The commenter provided the example of making the procedure for prescribing certain formulary drugs very easy and straightforward, while attempts to prescribe other formulary drugs trigger multiple pop-up notices or require a series of additional steps.

Response: We do not believe it would be feasible or appropriate to regulate the content of commercial messaging or

formulary compliance activities through these exceptions to the physician self-referral law. The regulation of speech is outside the scope of this rulemaking. Nor, in any event, would a condition in these exceptions related to the accuracy or objectivity of the content of messages or formulary activities be sufficiently "bright line" to be practical or readily enforceable. Nothing in this rulemaking should be construed to authorize or approve any commercial messaging, formulary compliance activity (or any other conduct) that is prohibited by any Federal, State, or local law or regulation. Moreover, technology used for marketing purposes would not meet the "necessary and used solely" standard required by the MMA for the electronic prescribing exception because marketing information is not the type of clinical support that is integral to prescribing accurate and appropriate items and services for patients.

d. Other Conditions

Comment: Many commenters supported the prohibition against donors or their agents taking any actions to disable or limit interoperability or otherwise impose barriers to compatibility.

Response: We agree, and we are retaining this requirement in the final exception.

Comment: Commenters generally agreed that the provision of equipment for personal, nonmedical purposes should not be protected.

Response: The exception does not protect the provision of technology for personal, nonmedical purposes.

6. Multifunctional Technology

We proposed using our regulatory authority under section 1877(b)(4) of the Act to create an additional exception to protect the provision by DHS entities to physician recipients of some limited hardware (including necessary operating system software) and connectivity services that are used for more than one function, as long as a substantial use of the item or service would be to receive or transmit electronic prescription information.

Comment: Most commenters supported a single exception that would extend protection to technology beyond what is "necessary and used solely" for electronic prescribing. Many commenters expressed the hope that multifunctional technology ultimately would be captured in an electronic health records technology exception.

Response: We have decided not to create a separate exception for multifunctional technology. Instead, we are creating a new exception for the

protection of certain arrangements involving electronic health records software, information technology and training services (including connectivity services) that will serve more directly to further the overall goal of widespread adoption of interoperable electronic health records technology without some of the program or patient abuse risks inherent in gifts of multifunctional hardware. Our review of the totality of the public comments supports this approach, as more fully described in the next section.

D. Summary of the Final Provisions Related to § 411.357(v)

This final rule at § 411.357(v) contains one exception for items and services that are necessary and used solely to receive and transmit electronic prescription information. The exception mirrors the MMA language and protects donations of hardware, software, internet connectivity, and training and support services, provided that the technology meets the applicable standards under Medicare Part D at the time the items and services are donated. (See November 7, 2005 final rule (70 FR 67568) for the current, or "foundation," standards.) Further, donations may not take into account, directly or indirectly, the volume or value of referrals from the physician or other business generated between the parties. We have not placed a monetary limit on the value of donations of electronic prescribing technology. We have retained most of the key provisions from the proposed rule; however, the final rule does not include a requirement for physician certification of technical and functional non-equivalence. We emphasize that: (1) The final rule protects technology necessary and used solely to receive and transmit *any* prescription information, whether related to drugs or to other items or services normally ordered by prescription; and (2) donations may be in an unlimited amount.

We are *not* finalizing a separate exception for multifunctional electronic prescribing technology.

IV. Response to Comments and Final Rule Provisions Regarding Electronic Health Records Exception (Proposed § 411.357(w))

A. Summary of the Proposed Provisions Related to § 411.357(w)

Prior to publication of the proposed rule, many in the hospital industry, among others, raised the issue of the need for protection under an exception for arrangements involving technology other than electronic prescribing. To encourage the adoption of electronic

health records technology consistent with the ultimate goal of achieving fully interoperable electronic health records for all patients, we proposed using our legal authority at section 1877(b)(4) of the Act to issue two exceptions related to electronic health records software and training services that are necessary and used to receive, transmit, and maintain electronic health records of the donor's or physician's patients. We did not propose protecting hardware in either exception, because we believe electronic health records software and training services are the components of electronic health records systems most likely to be needed by physicians, and because donations of valuable, multifunctional hardware (such as computers and servers) would inherently pose a higher risk of constituting a disguised payment for referrals. The first proposed exception would have applied to donations made before the Secretary adopts product certification criteria, including criteria for interoperability, functionality, and privacy and security of electronic health records technology. (In the proposed rule (70 FR 59197), we referred to this proposed exception as the "pre-interoperability" exception.) We proposed the following:

- That the electronic health records software must be necessary and used solely for the transmission, receipt, and maintenance of patients' electronic health records and prescription drug information.
 - Defining "necessary" consistent with the definition of the term in the proposed exception for electronic prescribing arrangements.
- That the software would have to include an electronic prescribing component that meets the applicable standards under Medicare Part D at the time the software is donated.
 - That the pre-interoperability exception would not protect the provision of other types of technology (for example, billing, scheduling, or general office management software) or any software or staff used by the physician to conduct business or engage in activities unrelated to the physician's medical practice. We also proposed that the exception would not protect the provision of staff to the physician or the physician's office.
 - Defining the term "electronic health records" and we solicited comments on an appropriate definition.
 - Including documentation provisions comparable to those proposed for the electronic prescribing exception.
 - Prohibiting protection for any arrangement in which the donor (or any

person on the donor's behalf) disabled the interoperability of any component of the software or otherwise imposed barriers to compatibility.

- Limiting the aggregate value of protected technology that a donor could provide to a physician under the pre-interoperability exception or in combination with the other proposed exceptions. We noted that we were considering the same alternatives for setting a value limit that were proposed for the electronic prescribing exception. These could include: An aggregate dollar cap; a limitation that would require cost sharing by the physician; or another methodology, for example, a reduction in the amount of any cap over time.

- Including the same categories of donors and physician recipients that we proposed for the electronic prescribing exception.

- Including other requirements drawn from the proposed electronic prescribing exception, for example, the restriction on arrangements tied to the volume or value of referrals or other business generated between the donor and recipient (proposed § 411.357(x)(4)); a prohibition on conditioning business on the receipt of technology (proposed § 411.357(x)(3)); and an all payors condition (proposed § 411.357(x)(7)).

- Sunsetting the pre-interoperability exception once product certification criteria were finalized.

Recognizing that some enhanced flexibility in the conditions applicable under an exception for electronic health records arrangements might be appropriate once standards and product certification criteria were developed for electronic health records (including standards for interoperability) and adopted by the Secretary, we proposed a second exception that we referred to as the "post-interoperability" exception. We noted that adoption of uniform interoperability standards, as well as product certification criteria to ensure that products meet those standards, would help prevent technology from being used by unscrupulous parties to lock in streams of referrals or other business. In summary, we proposed the following for the post-interoperability exception:

- That protected technology must be certified in accordance with product certification criteria adopted by the Secretary, and must include an electronic prescribing component that complies with applicable electronic prescribing standards established by the Secretary for the Part D program, to the extent that those standards are not incorporated into the product certification criteria.

- That the same conditions proposed for the pre-interoperability exception would apply, with the following exceptions: (1) We proposed including some additional software applications as long as electronic health records and electronic prescribing remain core functions; (2) we proposed including additional categories of donors and physician recipients; (3) we proposed including specific selection criteria to identify acceptable methods for selecting physician recipients; and (4) we proposed a potentially larger limit on the value of protected technology.

We also proposed and solicited public comment on the scope and conditions for the electronic health records exceptions.

As noted previously in this preamble and in the proposed rule, our decision to propose these exceptions did not reflect a view that all electronic health records arrangements would require protection under an exception to the physician self-referral law. Moreover, in many cases, such arrangements may qualify for such protection under existing exceptions or may not implicate the physician self-referral law.

B. General Comments

Comment: Most commenters expressed concern with the pre- and post-interoperability bifurcated approach to the exceptions, asserting that a bifurcated approach was not necessary, too confusing, and/or contrary to the goal of achieving widespread adoption of health information technology. These commenters urged us to abandon the bifurcated approach and to publish one final exception for remuneration in the form of electronic health records technology. Commenters urged us and the OIG to adopt similar approaches to a post-interoperability exception under the physician self-referral law and a post-interoperability safe harbor under the anti-kickback statute.

Response: We have finalized one exception for arrangements involving the donation of electronic health records software or information technology and training services at § 411.357(w).

Comment: Some commenters suggested that we incorporate the general concept of interoperability into the pre-interoperability exception, even if we do not require product certification. Many commenters stated that encouraging electronic health records arrangements before interoperability standards are available would be undesirable public policy. Some commenters believe that a product certification process that would include interoperability standards is

already underway and within the timeframe for this rulemaking. Others expressed that we should either not wait until certification standards are adopted before finalizing the post-interoperability exception, or not finalize either of the exceptions until the certification standards are adopted. One commenter expressed that, since timetables for the rulemaking and for the certification standards are not known, we should consider promulgating the regulation from the pre-interoperability perspective and address the post-interoperability era in the future.

Response: We agree with the commenters that a bifurcated approach is not necessary. We are not promulgating separate exceptions for pre- and post-interoperability as we had proposed in the October 11, 2005 proposed rule. The industry has made considerable progress in developing certification criteria for electronic health records products within a very short time. In fact, one certification organization has already completed an initial set of certification criteria for ambulatory electronic health records. In some cases, there may be products for which no certification criteria are available. To address this situation, and to ensure interoperability to the extent possible, the final exception requires that donated software be interoperable at the time of the donation (regardless of whether the product is actually certified), and bars a donor or any entity on its behalf from taking any actions to disable or limit interoperability. This latter condition also protects against donors that improperly may attempt to create closed or limited electronic health records systems by offering technology that functionally or practically locks in business for the donor.

Comment: Many commenters supported the proposed prohibition against donors or their agents taking any actions to disable or limit interoperability or otherwise impose barriers to compatibility of the donated technology with other technology, including technology owned or operated by competing providers and suppliers.

Response: We have included this requirement in the final exception. We believe this condition helps ensure that remunerative arrangements involving health information technology will further the policy goal of fully interoperable health information systems and will not be misused to steer Medicare referrals to the donor.

Comment: Some commenters suggested that early adopters of electronic health records technology

should be offered incentives or rewards because, otherwise, physicians might delay investing their own funds in electronic health records systems while waiting for a donor to offer them free technology. The commenters continued that this delay would have a detrimental effect on the adoption of electronic health records technology.

Response: It is unclear what types of incentives or rewards the commenters are requesting. We note that the exception does not provide incentives or rewards, nor would it be appropriate for an exception to do so; rather, the exception protects the donation of certain electronic health records technology when all conditions of the exception are satisfied. The exception would not protect any cash reimbursement paid to physician recipients for costs they incurred in adopting technology.

Comment: One commenter requested that we and the OIG coordinate with the Internal Revenue Service (“IRS”) to provide guidance through an IRS revenue ruling publication to alleviate concerns related to tax exemption.

Response: The commenter should contact the IRS directly with its concerns.

C. Specific Comments

1. Protected Compensation in the Form of Items or Services (Nonmonetary Remuneration)

a. Covered Technology

We proposed protecting the donation of electronic health records software and directly related training services that are necessary to receive, transmit, and maintain electronic health records of the entity’s or physician’s patients, provided that the software includes an electronic prescribing component. Importantly, we stated our intention to protect donations of systems that improve patient care rather than of systems comprised solely or primarily of technology that is incidental to the core functions of electronic prescribing and electronic health records.

Comment: Some commenters asked whether our proposal to protect certain technology necessary and used to “receive, transmit, and maintain” electronic health records would include technology used to develop, implement, operate, facilitate, produce, and supplement electronic health records.

Response: We intended that the final rule would encompass the types of uses described by the commenters. To make this intent clear, we have clarified the final rule to provide that the protected technology must be necessary and used predominantly to “create, maintain,

transmit, or receive” electronic health records.

Comment: Most commenters believe that the proposed scope of protected remuneration was too narrow. A few commenters suggested that we limit the scope of the protected technology.

Commenters variously suggested that the exception should also protect remuneration in the form of hardware, operating software, connectivity items, support services, secure messaging, storage devices, clinical decision support technology, services related to training and ongoing maintenance, rights, licenses, and intellectual property, as well as interfaces and translation software to allow physician offices to exchange data with hospital systems, all of which the commenters considered necessary for a fully-functioning electronic health records system.

Some commenters encouraged us to exclude from protection hardware and broadband wireless internet connectivity and to tailor the protection of this exception narrowly to cover software, training, and information technology support services. One commenter opined that ongoing support, such as help desk support, could pose a risk of abuse, because the physician would become dependent on the donor for the help desk support, and might feel obligated to refer to the donor to ensure continuation of that support. This commenter suggested that we protect initial, start-up support services, but not long-term, ongoing system support. A few commenters suggested that the scope of support services, training, and other items and services should be a defined contribution not to exceed 365 person-days.

Response: We have carefully considered the comments in light of our intention to promote the adoption of electronic health records without risk of program or patient abuse. The final rule protects electronic health records software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records.

To ensure that the exception is only available for software, information technology and training services that are closely related to electronic health records, the exception provides that electronic health records functions must predominate. The core functionality of the technology must be the creation, maintenance, transmission, or receipt of individual patients’ electronic health records. In addition, the donated software must have electronic prescribing capability, either through an

electronic prescribing component or the ability to interface with the physician’s existing electronic prescribing system, that meets the applicable standards under Medicare Part D at the time the items and services are provided.

Although electronic health records purposes must predominate, protected software packages may also include other software and functionality directly related to the care and treatment of individual patients (for example, patient administration, scheduling functions, billing, clinical support software, etc.). This condition recognizes that it is common for electronic health records software to be integrated with other features.

We interpret “software, information technology and training services necessary and used predominantly” to include, by way of example, the following:

- Interface and translation software;
- Rights, licenses, and intellectual property related to electronic health records software;
- Connectivity services, including broadband and wireless internet services;
- Clinical support and information services related to patient care (but not separate research or marketing support services);
- Maintenance services;
- Secure messaging (for example, permitting physicians to communicate with patients through electronic messaging); and
- Training and support services (such as access to help desk services).

We interpret the scope of covered electronic health records technology to exclude—

- Hardware (and operating software that makes the hardware function);
- Storage devices;
- Software with core functionality other than electronic health records (for example, human resources or payroll software); and
- Items or services used by a physician primarily to conduct personal business or business unrelated to the physician’s practice.

Further, training and support services do not include the provision of staff to physicians or their offices. For example, the exception would not protect the provision of staff to transfer paper records to the electronic format. We believe that most physicians already possess the hardware necessary to operate electronic health records systems. Moreover, hardware represents a much lower cost to the physician when compared to electronic health records software. Requiring investment by a physician recipient in the hardware

portion of the electronic health records system safeguards further against program abuse.

Finally, consistent with our discussion in the proposed rule and our goal of widespread adoption of electronic health records, we are not protecting systems comprised solely or primarily of technology that is incidental to electronic prescribing and electronic health records. As previously discussed, we intend that this exception protect electronic health records technology arrangements in which the electronic health records component predominates.

Although we share the concerns of those commenters that ongoing remuneration, such as maintenance and help desk support, creates long-term remunerative ties between donors and recipients, we believe that requiring donated electronic health records to be interoperable protects against the "tying" of referral sources (physicians) to donor entities seeking referrals. Further, the cost sharing requirement and sunset provision in the final electronic health records exception should also address this concern.

Comment: With respect to internet connectivity services, some commenters suggested that donations for connectivity should be limited to any necessary devices for connectivity and technical support for selecting and installing the appropriate connectivity services, but should not include connectivity fees, which should be an ongoing expense of the physician. Other commenters suggested that covered technology should include "T1" lines or other enhanced broadband connectivity (including connectivity needed to transfer medical images and EKGs (especially in rural areas)), routers to speed download times, secure connections and messaging, and ongoing maintenance and support and interfaces.

Response: The final exception protects the donation of all forms of connectivity services. We believe the choice of appropriate connectivity services is an individual determination best made by the donors and physician recipients given their specific circumstances. We note that the cost sharing requirement of § 411.357(w)(4) will apply to these services, including connectivity fees. The exception does not protect routers or modems necessary to access or enhance connectivity because hardware is not protected remuneration under the exception. As noted in the preceding response, concerns about ongoing donations of connectivity services are also addressed by the sunset provision.

Comment: Several commenters urged us to protect arrangements involving the donation of billing software and other software for administrative functions, such as registration and patient scheduling, because much of the "return on investment" (that is, value) for physicians who incorporate an electronic health records system into their practices is the integration of clinical and administrative systems. Commenters noted that the scope of the exception should account for the fact that the products on the market increasingly integrate administrative functions with the clinical electronic health records functions. One commenter suggested that the exception should at least prohibit the donation of technology that is unrelated to the actual electronic health records software, such as technology related to office administration. The commenter requested that the exception protect integrated bundles of applications that include an electronic health records component, provided the physician pays for the technology that is unrelated to the electronic health records software. Another commenter suggested that the exception should not protect clearly separable administrative software (for example, billing, coding, and practice management software), but protect those elements of an electronic health records system that incidentally facilitate administrative functions, such as software that links to diagnosis codes for billing purposes. The commenter suggested that these functions that dually support patient care and practice administration are valuable to the physician and a driving force behind adoption of electronic health records systems.

Response: As previously noted, the final exception protects the donation of electronic health records software packages that include core functionality of electronic prescribing and the creation and maintenance of individual patients' electronic health records. Protected software packages may also include other software and functionality directly related to the care and treatment of individual patients (for example, patient administration, scheduling functions, billing, clinical support software, etc.).

Comment: A commenter asked for further clarification on whether the exception would cover the donation of an electronic health records system operating within an "Application Service Provider" model.

Response: Subject to the cost sharing requirement and other conditions of the final exception, we would consider the donation of an electronic health records

system operating within an "Application Service Provider" model (a business model that provides computer-based services over a network) as covered technology.

Comment: A few commenters requested that the final rule require donors to provide data migration services to a physician if the physician chooses to abandon the donated electronic health records system and purchase his or her own electronic health records system.

Response: We believe it is not appropriate to require donors to provide data migration or any other specific service to physicians who choose to switch electronic health records systems. Donors may provide services if they wish, as long as the arrangement otherwise complies with the exception. We note that, to the extent the data migration services involve the provision of staff to the physician's office in order to transfer the data, the services would not be protected.

Comment: A commenter recommended that the exception specifically protect the provision of patient portal software that enables patients to maintain on-line personal medical records, including scheduling functions.

Response: Nothing in this final exception precludes protection for patient portal software if it meets all conditions of the exception.

Comment: Some commenters urged us to remove the proposed requirement that an electronic health records system include an electronic prescribing component because such a requirement may stifle investment in electronic health records technology in situations where electronic prescribing is not considered a significant need. These commenters suggested that patients would benefit most if we permit donors to first adopt electronic health records technology and then add electronic prescribing. Other commenters supported making an electronic prescribing component a mandatory part of the donated electronic health records system.

Response: Nothing in this exception prevents donors from adopting any particular form of technology. However, to qualify for the protection of this exception for arrangements in which the donor provides electronic health records technology to potential referral sources, we are requiring that the donated electronic health records system include electronic prescribing capacity, either in an electronic prescribing component or the ability to interface with the physician's existing electronic prescribing system that meets the

II.A.1 of the proposed rule in the exception for electronic prescribing.

Comment: Some commenters asked whether our proposal to protect certain technology necessary and used to “receive, transmit, and maintain” electronic health records would include technology used to develop, implement, operate, facilitate, produce, and supplement electronic health records.

Response: We intend that the final rule will encompass the types of uses described by the commenters. To make this intent clear, we have clarified the final rule to provide that the protected technology must be necessary and used predominantly to “create, maintain, transmit, or receive” electronic health records.

Comment: One commenter requested that we clarify that the term “necessary” would not preclude the provision of outpatient-focused (also referred to as “ambulatory-focused”) electronic health records software to physicians who may already have access through the internet or otherwise to an inpatient-focused electronic health records systems.

Response: The final rule does not preclude the provision of outpatient or ambulatory electronic health records software to physicians who already have access to inpatient-focused systems.

2. Technical and Functional Equivalence

We proposed requiring the physician recipient of donated electronic health records technology to certify that the items and services to be provided are not technically or functionally equivalent to items or services the physician already possesses or has obtained. The proposed exception would have required that the certification be updated before the provision of any necessary upgrades or items and services not reflected in the original certification. We expressed our concern that the certification process would be ineffective as a safeguard against program or patient abuse if it were a mere formality or if physicians simply executed a form certification provided by a donor. Therefore, we proposed that the donor must not have actual knowledge of, and 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 and that the exception would protect the physician only if the certification were truthful.

Comment: Several commenters requested further clarification regarding the meaning of “technically or functionally equivalent” and the

meaning of “significantly enhance the functionality” as we used those terms in the proposed rule. Other commenters expressed concerns about the requirement, asserting that it would deter physicians who are not technology experts from adopting health information technology, and might result in physicians hiring costly technology consultants to evaluate their existing systems. A commenter expressed concern that the exception not hinder the goals of widespread adoption of electronic health records by, for example, excluding from protection technology that would standardize the technology used by all physician recipients or updated, user-friendly technology that would replace outdated, outmoded, or unusable technology. For these reasons, several commenters stated that technical and functional equivalence was not an appropriate or workable standard for assessing whether donated items and services are necessary and that, accordingly, the requirement should not be adopted.

Other commenters suggested modifications to the proposed rule. One commenter suggested that hospitals should incorporate inquiries regarding the technological items and services physicians possess into the surveys physicians must complete to acquire and maintain physician privileges. Another suggested that any costs associated with the certification process should be included as part of the services offered by the donor. A few commenters suggested that we should provide financial assistance in evaluating the existing technology, while another commenter proposed that we publish guidelines for technological equivalence upon which all donors and physicians could rely. Some commenters urged that the certification requirement incorporate a “good faith” standard for compliance, while other commenters expressed concern that donors would not be in a position to evaluate the technology already possessed by potential physician recipients and, therefore, that protection under this exception for donors should not hinge on the physician’s certification. Another commenter requested that we provide “templates” for the written certification to ensure a simple and transparent certification process. One commenter expressed concern that a requirement for ongoing certification to account for upgrades or new software, hardware, or services would create an unnecessary burden. Another commenter proposed that there should be one certification required once interoperability standards for all

health information technology components are finalized.

Response: Having considered the public comments, we have concluded that our proposal to require physicians to certify in writing that they do not possess equivalent technology might become unnecessarily burdensome. We are not requiring a written certification. The final exception requires that protected donations be limited to electronic health records software or information technology and training services that are necessary and used predominantly to create, maintain, transmit, or receive electronic health records. We do not believe software and services are “necessary” if the physician recipient already possesses the equivalent software or services. The provision of equivalent items and services poses a risk of abuse, since such arrangements potentially confer independent value on the recipient (that is, the value of the existing items and services that might be put to other uses) unrelated to the need for electronic health records technology. Thus, if a donor knows that the physician already possesses the equivalent items or services, or acts in deliberate ignorance or reckless disregard of that fact, the donor will not be protected by the exception. Thus, prudent donors may want to make reasonable inquiries to potential physician recipients and document the communications. We do not believe this requirement necessitates the hiring of technical experts by either the donor or physician recipient.

The final exception would not preclude upgrades of items or services that enhance the functionality of the physician’s existing technology, including upgrades that make software more user-friendly or current, nor would it preclude items and services that result in standardization of systems among donors and physicians, provided that the standardization enhances the functionality of the electronic health records system (and any donated software is interoperable).

Comment: Many commenters requested further clarification of our concern about the risk of physicians intentionally divesting themselves of technically or functionally equivalent technology that they already possess or have obtained in order to shift costs to the donor. (See October 11, 2005 proposed rule, (70 FR 59188).) These commenters expressed the opinion that physicians would not intentionally divest themselves of health information technology given the low adoption rate of health information technology and the time and resource commitment

necessary to implement and maintain a health information technology system.

Response: Although we believe that there is a real potential for a physician to divest intentionally himself or herself of health information technology to shift the costs to a donor, we are not including any specific conditions to address such divestiture. Rather, we believe that the totality of the conditions in the final exception, including, for example, the cost sharing requirement and the sunset provision, should adequately address our concerns. We believe that physicians, acting as prudent buyers, are less likely to divest themselves of technology for which they would have to contribute to the replacement cost.

d. Interoperability/Standards

The implementation of electronic health information technology is a national priority that has the potential to improve our health care 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.

As discussed in the proposed rule, 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 also 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 clinical decision-making inappropriately. We proposed two types of conditions that would make compatibility and interoperability of donated technology key features of protected arrangements. These features would encourage the adoption of open, interconnected, interoperable systems, and thereby reduce the risk of fraud and

abuse. First, we proposed that once interoperability and other product criteria have been recognized, electronic health records technology should be certified in accordance with standards adopted by the Secretary. Second, we proposed that a donor (or entity acting on behalf of the donor) not limit or restrict the use of the technology with other electronic prescription or health records systems, or otherwise impose barriers to compatibility.

Comment: Many commenters advocated a requirement that all donations meet the Certification Commission for Healthcare Information Technology (CCHIT) approved certification levels of functionality, interoperability, and security. One commenter suggested that we measure interoperability based on accepted, consensus-driven standards that are already in place, such as the Electronic Health Record-Lab Interoperability and Connectivity Standards or other interoperability standards adopted by the Federal government as part of the Consolidated Health Informatics initiative (see <http://i777777o 8 873o 7 healthit/chi.html>). Some commenters expressed concern that clinicians who adopt health information technology before the existence of final certification standards would be unfairly penalized. These commenters were also concerned about the chilling effect on some early adoption arrangements where certification standards are not yet available. These commenters requested that we consider "grandfathering" clinicians whose existing health information technology systems are not compliant with the certification standards by permitting them a one-time opportunity to upgrade their systems to be compliant with CCHIT certification criteria. As an alternative to requiring CCHIT certification, a few commenters recommended that we condition the ongoing use of the exception on the donated software being capable of exchanging health care information in compliance with applicable standards once adopted by the Secretary and on no action being taken that would pose a barrier to the information exchange.

Response: Having considered the options, and consistent with Department policy, we have concluded that software will qualify for the protection of the exception if it is interoperable as defined in this final rule. Software will be deemed to be interoperable if it is certified by a certifying body recognized by the Secretary. Nothing in the final rule precludes donors from providing physicians with upgrades to software that meet the definition of

"interoperable" or would make the software comply with then-existing certification standards.

Comment: We indicated in the October 11, 2005 proposed rule (70 FR 59186) that we were considering defining the term "interoperable" for purposes of the exception 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." One commenter agreed with this proposed definition. Another commenter suggested that we adopt the definition developed by the National Alliance for Health Information Technology (NAHIT): "the ability of different information technology systems and software applications to communicate, to exchange data accurately, effectively, and consistently, and to use the information that has been exchanged." One commenter suggested that the definition of interoperability be flexible enough to adapt to evolving industry standards. A few commenters suggested defining interoperability as "the uniform and efficient movement of electronic healthcare data from one system to another, such that clinical or operational purpose and meaning of the data is preserved and unaltered." One commenter opposed any definition of interoperability that would require a donor to support electronic transmissions from technology supplied by other vendors or to host applications accessible by software supplied by other vendors.

Response: Having reviewed the public comments and upon further consideration, we are defining "interoperable" to mean that, at the time of the donation, the software is "able to (1) communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings, and (2) exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered."

Interoperability must apply in various settings, meaning that the software must be interoperable with respect to systems, applications, and networks that are both internal and external to the donor's or physician recipient's systems, applications, and networks. In other words, software will not be considered interoperable if it is capable of communicating or exchanging data only within a limited health care system or community.

We believe this definition reflects our intent to protect only those

arrangements that will foster 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 undue risk that donors might use arrangements to lock in referrals from physician recipients.

We are mindful that the ability of software to be interoperable is evolving as technology develops. In assessing whether software is interoperable, we believe the appropriate inquiry is whether the software is as interoperable as feasible given the prevailing state of technology at the time the items or services are provided to the physician recipient. Parties should have a reasonable basis for determining that software is interoperable. We believe it would be appropriate—and, indeed, advisable—for parties to consult any standards and criteria related to interoperability recognized by the Department. Compliance with these standards and criteria will provide greater certainty to donors and recipients that products meet the interoperability requirement, and may be relevant in an enforcement action. We note further that parties wishing to avoid any uncertainty can avail themselves of the “deeming” provision, which provides that software that is certified by a body recognized by the Secretary will be deemed to be interoperable for purposes of the exception. In order to ensure interoperability, products must have an up-to-date certification at the time of donation, and we are requiring that, to meet the deeming provision, the software must have been certified within 12 months prior to the date of the donation.

We are including the condition that the donor (or any person on the donor’s behalf) must not take any actions to limit or restrict the ability of the items or services to be interoperable with other electronic prescription information items or services or electronic health information systems. We believe this condition clearly reflects our intent that donors should not limit or restrict the use, compatibility, or interoperability of donated technology. We note that compliance with the condition in § 411.357(w)(3) is a separate requirement from compliance with § 411.357(w)(2), which requires that products must be interoperable and will be deemed interoperable if a certifying body recognized by the Secretary has certified the software within no more than 12 months prior to the date it is provided to the physician. For example, if a donor takes actions that would

cause a certified product to fall out of compliance with the interoperability standards that apply to the certified product, we would consider that to be an action to limit or restrict the use or compatibility of the items or services for purposes of § 411.357(w)(3). We are not persuaded to protect arrangements where use, compatibility, or interoperability is limited to the products of specific vendors. To the contrary, we believe that inherent in the concept of interoperability is the ability of technology to communicate with products of other vendors.

Comment: Many commenters supported the proposed prohibition against donors or their agents taking any actions to disable or limit interoperability or otherwise impose barriers to compatibility of the donated technology with other technology, including technology owned or operated by competing providers and suppliers.

Response: We have revised § 411.357(w)(3) to clarify this requirement in the final exception. We believe this condition will help ensure that donations of health information technology will further the policy goal of fully interoperable health information systems and will not be misused to steer business to the donor.

2. Permissible Donors and Physician Recipients

a. Donors

We proposed to limit the scope of protected donors under the electronic health records exception to hospitals, group practices, PDP sponsors, and MA organizations, consistent with the MMA-mandated donors for the electronic prescribing exception. We indicated that we selected these donors because they have a direct and primary patient care relationship and a central role in the health care delivery infrastructure that would justify protection under the exception for the provision of electronic health records technology that would not be appropriate for other types of providers and suppliers, including providers and suppliers of ancillary services.

Comment: Most commenters stated that the proposed scope of potential donors was too limited. Commenters variously suggested that the protected donors include some or all of the following categories:

- Nursing facilities;
- Assisted living and residential care facilities;
- Intermediate care facilities for persons with mental retardation;
- Mental health facilities;
- Organizations providing population health management services (such as

disease and care management programs and services);

- All components of an integrated delivery system (“IDS”) (including network providers or other entities that operate, support, or manage network providers);

- Clinical laboratories;
- Pharmaceutical manufacturers;
- Durable medical equipment

suppliers;

- Radiation oncology centers;
- Community health centers;
- Physician-hospital organizations;
- Health plans;
- Regional Health Information

Organizations (“RHIOs”);

- Dialysis facilities; and

- Other entities that, in the

commenters’ views, enhance the overall health of a community.

One commenter representing dialysis facilities suggested that the exception should protect donations of nonmonetary remuneration by all providers that maintain medical staffs pursuant to medical staff bylaws when the donations are made to members of the medical staff. Another commenter suggested that a clinical data exchange (or community-wide health information system) should be included as a protected donor, because individual stakeholders in health information technology projects are unlikely to develop, purchase, or donate items necessary to implement and maintain a true community-wide clinical data exchange. A few commenters stated that health plans and pharmacy benefits managers (PBMs) should be protected donors because, according to the commenters, these entities develop health information technology and are engaged with physicians on a direct level to increase the utilization of electronic prescribing and electronic health records technology. These commenters urged that the risk to the Medicare program and its beneficiaries is reduced because health plans and PBMs have business incentives to limit utilization of prescriptions. A few commenters suggested that we should permit any entity that has an interest in donating health information technology to do so.

Response: Recognizing that extending the protection of the exception to a wider group of donors may further facilitate the dissemination of the technology and after carefully considering the recommendations of the commenters, we have expanded the list of protected donors. In an effort to create a bright line rule, protected donors include all entities (as that term is defined at § 411.351) that furnish DHS. DHS entities may donate covered

technology to any physician. To the extent that a PDP sponsor or MA organization is an entity that furnishes DHS, donations of electronic health records software or information technology and services by the PDP sponsor or MA organization would be permissible, provided that all conditions of the exception are met. (When PDP sponsors and MA organizations do not satisfy that definition, the physician self-referral prohibition may not be implicated.) Moreover, PDP sponsors and MA organizations potentially may avail themselves of other existing exceptions.

In identifying the final list of protected donors, we considered the important goal of encouraging the rapid adoption of interoperable electronic health records by physicians and other providers. We believe that, although some types of DHS entities may have a more direct and central role in the provision of care to patients than other DHS entities, the goal of widespread adoption of interoperable electronic health records is sufficiently important to permit all types of DHS entities to donate covered technology. Expanding the list of permissible donors beyond those identified in the proposed rule will expedite adoption of electronic health records. We also believe that our concerns about the potential for increased utilization or anticompetitive behavior that could arise from permitting an expanded list of donors to donate electronic health records technology are addressed through the additional conditions and limitations included in the final rule. Specifically, we believe that the requirements that donated software be interoperable and that physicians contribute 15 percent to the cost of the donated technology, and the limited duration of the exception (it sunsets on December 31, 2013), if met, provide adequate protection against program and patient abuse. We caution that compliance with *each* condition of the exception is mandatory in order for an arrangement to enjoy the protection of the exception. We are not expanding the list of protected donors to include every type of health care entity requested by the commenters as the physician self-referral law does not apply to many of the suggested entities (for example, pharmaceutical manufacturers and RHIOs). In addition, as discussed in this preamble, protection under this exception may not be needed for all arrangements involving the provision of electronic health records items and services.

Comment: A commenter requested that Federally qualified health clinics (FQHCs), as defined in the Medicaid

statute and Medicare regulations, should be included as permissible donors.

Response: As entities furnishing DHS, FQHCs are protected donors under the final rule.

Comment: A commenter requested that we expand the list of permissible donors to include research and manufacturing entities and suggested that blind trusts could be established utilizing funds from several pharmaceutical companies to reduce the risk of program or patient abuse. Another commenter requested that we include entities in the research-based biopharmaceutical industry as permissible donors, noting that the widespread adoption of health information technology could reduce the need for proprietary systems used solely for purposes of clinical trial programs. One commenter requested that health information technology vendors be included as protected donors.

Response: We are not including research and manufacturing entities, entities in the research-based biopharmaceutical industry, or health information technology vendors as protected donors for purposes of this final exception because they are not subject to the prohibitions of the physician self-referral law as they are not entities furnishing DHS. With respect to the establishment of blind trusts, such arrangements would be outside the scope of this rulemaking.

Comment: One commenter strongly urged us to expand the list of protected donors to give physicians the opportunity to choose between different software offerings. Other commenters suggested that the exception should require an open, transparent Request for Proposal ("RFP") process whereby the donating entity would be required to offer technology from a minimum of three vendors for the physician to select. These commenters expressed the view that a multivendor, open RFP process would ensure competitive market pricing and would allow physicians to participate in the selection process to ensure that services meet the needs of their clinical practices, while also protecting against the physician being locked in by the donating entity. Another commenter requested that the final rule clearly state that physicians should be free to choose their own electronic health records systems or should be offered a choice by entities providing subsidies or assistance for purchasing these systems.

Response: Physicians remain free to choose any electronic health information technology that suits their

needs. However, we are not requiring donors to facilitate that choice for purposes of the exception, although donors must offer interoperable products and must not impede the interoperability of any technology they decide to offer. We decline to require the type of RFP process requested by the commenter, as it would be unnecessarily complex, burdensome and impractical, and would increase significantly the transaction costs for donating electronic health records technology. In addition, nothing in this exception requires donors to donate any particular level, scope, or combination of items and services.

Comment: Commenters from the laboratory industry strongly urged us to include laboratories as protected donors. They argued that reducing duplicative laboratory testing is a potential benefit to the implementation of interoperable electronic health records. These commenters stated that clinical laboratories should be included in the exception to achieve a level playing field and the goal of widespread adoption of technology.

Response: Because clinical laboratories are entities furnishing DHS, we are including them as permissible donors under the final exception.

Comment: A commenter suggested that the exception should protect nonmonetary remuneration offered by partnerships or consortia of otherwise permissible donors, so that parties could work together and share the cost of expanding needed health information technology in the community.

Response: We discern nothing in the final exception that necessarily would preclude a partnership or consortium of otherwise permissible donors from entering into a protected arrangement, provided the conditions of the exception are satisfied.

b. Physician Recipients

Comment: Most commenters expressed the view that the categories of protected physician recipients were too limited and urged us to be more expansive. Commenters suggested that some or all of the following should be included as permissible recipients:

- Nonmedical staff physicians;
- Physicians who are network providers;
- Physicians who have contracted with an IDS;
- Physicians and other licensed health care professionals whose patients regularly receive inpatient and/or outpatient care at the donor hospital or health system;
- Hospitalists;
- Intensivists;

- Physician assistants;
- Nurse practitioners;
- Audiologists; and
- Independent contractors of group practices.

Commenters noted that many nonphysician providers would benefit greatly from protection under this exception, given the fact that nonphysician providers generally have limited resources available to fund office technology.

Response: We agree with the commenters who suggested expanding the list of protected physician recipients of donated technology to further the goal of, and achieve the benefits of, widespread adoption of electronic health information technology. The final rule permits donation of protected remuneration by an entity that furnishes DHS to any physician. Because the physician self-referral law only applies to donations to physicians, it is unnecessary for us to expand the exception to protect donations to nonphysicians.

Comment: Many commenters suggested that the categories of permissible recipients be expanded to include the following providers and suppliers and their staffs:

- Nursing facilities;
- Assisted living and residential care facilities;
- Intermediate care facilities for persons with mental retardation;
- Mental health facilities;
- Clinical laboratories;
- Durable medical equipment providers;
- Pharmacies, including long term care pharmacies;
- Community health centers;
- Network providers or other entities that operate, support or manage network providers;
- Physician-hospital organizations;
- Health plans;
- RHIOs; and
- Other entities designed to enhance the overall health of the community.

Commenters also requested that FQHCs, as defined in the Medicaid statute and Medicare regulations, should be included as permissible recipients.

Response: We decline to adopt the commenters' suggestion for permitting donations to these types of entities and their staffs. We note that the physician self-referral law applies only when a physician is a party to the financial (either compensation or ownership) arrangement. Donations to the types of entities suggested by the commenters for inclusion as permissible recipients under the final exception would not implicate the physician self-referral law if made by other nonphysician entities.

Comment: Many commenters requested that we permit donors to donate technology to all members of a group practice, or to the group practice as a whole, even if all members do not routinely provide services to the donor. Some commenters suggested that we should permit group practices to donate to other group practices. One commenter asked for clarification as to whether the proposed exception would apply only to the specific physician recipient of the donated technology or whether, for example, all members of a group practice could use the technology that was donated to the physician.

Response: The final rule contains no limitation on the physician's membership on a donor hospital's medical staff. The final exception does not protect donations from one group practice to another group practice; however, group practices, because they are entities that furnish DHS, may donate covered technology to any physician.

Comment: Some commenters stated that a hospital donor may not want to donate the full value of an electronic health records system to physicians outside of its medical staff. These commenters suggest permitting outside physicians to have access to the information in the hospital's electronic health records system by allowing the outside physicians to use or sublicense the hospital's electronic health records system at the cost to the hospital. These commenters also suggested allowing outside physicians to take advantage of the pricing obtained by the hospitals for electronic health records technology and related services.

Response: We have expanded the final exception to include all physicians as recipients when the donor is an entity that furnishes DHS. Nothing in the exception requires hospitals or other donors to offer physicians a full electronic health records system. We interpret the commenters' suggestion that community physicians be permitted to access electronic data at the hospital's cost to be a comment seeking clarification that any aggregate dollar limit on donated technology be calculated based on the donor's costs rather than retail value to the recipient. In this regard, the final exception incorporates a cost sharing requirement based on the donor's costs. It does not incorporate an aggregate dollar limit.

3. Selection of Physician Recipients

In light of the enhanced protection against program or patient abuse offered by interoperable electronic health records systems, this final rule permits donors to use selective criteria for

choosing physician recipients, provided that neither the eligibility of a physician, nor the amount or nature of the items or services donated, is determined in a manner that *directly* takes into account the volume or value of referrals or other business generated between the parties. We have enumerated several selection criteria which, if met, are 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 physician practices medicine or a determination based on the size of the physician's medical practice). Selection criteria that are based on the total number of prescriptions written by a physician are not prohibited. However, the final rule prohibits criteria based upon the number or value of prescriptions written by the physician that are dispensed or paid by the donor, as well as any criteria directly based on any other business generated between the parties. The final exception does not protect arrangements for which selection criteria are designed to induce a physician to change loyalties from other providers or plans to the donor.

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 electronic health records, while discouraging especially problematic direct correlations with Medicare referrals. This approach is a deliberate departure from other exceptions under the physician self-referral law 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 final 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 free or deeply discounted goods or services and the volume or value of referrals or other business generated between the parties are prohibited.

Comment: Several commenters commended us for our efforts to prevent program or patient abuse by prohibiting efforts to increase referrals or other changes in practice patterns. Some commenters noted that we should not allow donors to choose physicians selectively based upon the volume of their prescribing, size of practice, or

whether they would be likely to adopt the technology, and stated that donors should give technology to all physicians.

One commenter suggested eliminating the criteria permitting donors to select physicians based on any reasonable and verifiable manner that is not directly related to the volume or value of referrals or other business generated between the parties. The commenter stated that this criteria is too open-ended and subjective and could become a major loophole. Other commenters supported the use of such criteria and expressed the view that the use of selection criteria to select physician recipients will improve quality of care and ensure successful adoption of health information technology by physicians. These commenters offered suggestions on the standards for selection criteria. Some commenters suggested that we consider broad criteria for the selection of physicians, and that donors should be permitted to make this decision based upon their own financial model.

A commenter recommended that selection criteria related to the volume or value of referrals should be permitted, as long as the criteria are linked to achieving greater improvement in quality of patient care or greater success in adoption of health information technology. The commenter provided the following examples:

- Participation in hospital quality improvement activities;
- Participation in medical staff meetings and activities;
- Specialty;
- Department (if health information technology is rolled out by department);
- Readiness to use health information technology;
- Consistent use of hospital-based information technology systems;
- Acting as a “physician champion” of hospital-based information technology systems;
- Willingness to serve as a trainer for other physicians;
- Size of medical practice; or
- Willingness to contribute some resources to the health information technology project.

Another commenter requested that any list of criteria included in the rule be inclusive, rather than exclusive, and that we provide further guidance on how to interpret the criteria.

Response: Some of the commenters’ suggestions are too subjective, impractical, or not sufficiently bright-line to be “deeming” provisions for purposes of this rulemaking. Accordingly, those suggestions are not appropriate here. Although we believe it

is important to provide some guidance with respect to selection criteria, we do not believe it is possible to enumerate a comprehensive list. Therefore, we are providing several bright-line criteria in the final rule, along with a general provision that permits other reasonable and verifiable selection criteria that do not relate directly to the volume or value of referrals. We are finalizing the criteria enumerated in the proposed rule, in addition to a criterion related to the provision of uncompensated care, specifically—

- The determination is based on the total number of prescriptions written by the physician (but not the volume or value of prescriptions dispensed by the donor);
- The determination is based on the size of the physician’s medical practice (for example, total patients, total patient encounters, or total relative value units);
- The determination is based on the total number of hours that the physician practices medicine;
- The determination is based on the physician’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);
- The determination is based on whether the physician is a member of the donor’s medical staff, if the donor has a formal medical staff;
- The determination is based on the level of uncompensated care provided by the physician; or
- The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

Comment: Some commenters inquired whether the exception would permit a donor to offer a staggered rollout of electronic health records technology so that the technology could be provided on a selective basis, either by specialty, hospital department, or otherwise. These commenters suggested that the exception should not enumerate specific examples of instances when a staggered offering is deemed “not directly related to” referrals or other business, but rather should allow donors to offer health information technology as appropriate for each hospital’s individual financial situation.

Response: The final rule prohibits the selection of recipients using any method that takes into account directly the volume or value of referrals from the recipient or other business generated between the parties. The final rule provides some examples of acceptable criteria and permits any other determination that is reasonable and

verifiable. Given the potential variation in arrangements, it is not entirely clear to us how the commenters would implement their “staggered rollout.” Such arrangements should be evaluated for compliance with the exception on a case-by-case basis. We note that nothing in the exception requires that technology be provided to all potential recipients contemporaneously.

Comment: One commenter recommended that we reaffirm that physicians who receive donated technology remain free to choose what health information may or may not be shared with the hospital or entity providing the technology, consistent with current law and the wishes of patients and physicians.

Response: Nothing in this final rule regulates the sharing of health information. In addition, nothing in this final rule permits donors to influence the medical decision making of physicians or requires physicians to act in a manner that would violate any legal or ethical obligation to patients.

Comment: A commenter requested that we prohibit donors from selecting physicians in a manner that punishes or rewards past prescribing practices or influences their future prescribing practices. Another commenter recommended that we expressly permit any incidental increase to the volume of referrals resulting from increased quality and patient care.

Response: Any selection criteria directly related to past, present, or future volume of prescriptions dispensed or paid by the donor or billed to the Medicare program, or directly related to any other business generated between the parties, are strictly prohibited. Any selection criteria that punish or reward past prescribing practices or seeks to influence future prescribing practices would give rise to an inference that the selection criteria are tied directly to the volume or value of referrals. We are not adopting the commenter’s suggestion that we expressly permit increases in the volume of referrals attributable to increased quality in patient care. Whether an increase in the volume of referrals between a donor and physician recipient is attributable to increased quality in patient care, rather than an impermissible incentive, requires an evaluation of the particular facts and circumstances.

Comment: A commenter requested that PDP sponsors and MA organizations be permitted to determine eligibility, or the amount or nature of the items and services, in a manner that takes into account the volume and value of prescriptions written by the

physician that are paid by the PDP sponsor or MA organization. This commenter believes that PDP sponsors and MA organizations have the financial incentive to control drug utilization costs to compete effectively in the Medicare Part D marketplace.

Response: We are not persuaded by this commenter. Neither eligibility, nor the amount or nature of the items or services, may be determined by taking into account the volume or value of prescriptions written by the physician and paid by the PDP sponsor or MA organization. Nothing in the exception precludes PDP sponsors and MA organizations from offering protected items and services to physicians with whom they have network agreements.

Comment: One commenter requested that we protect donations when provided to a physician who provides a certain level of uncompensated care or a combination of uncompensated care and services to a certain number of Medicaid patients.

Response: The provision of uncompensated care would be an acceptable selection criterion and we have included it in the list of selection criteria deemed not to be directly related to the volume or value of referrals or other business generated between the donor and physician recipient. For example, a hospital can elect to provide technology only to rural and solo practitioners who provide high levels of uncompensated care when selecting among eligible physicians. The total number of Medicaid patients served by the practice could also be acceptable as long as there is no direct correlation with the number of Medicaid patients referred to the donor (or the value of the services provided). We do not believe it would be appropriate for us to establish a threshold level of uncompensated care necessary to qualify for protection under this exception. Donors should have flexibility to respond to the particular needs of their communities by selecting recipients based on levels of uncompensated care that reflect those needs.

4. Value of Technology: Cap

We proposed, as a further safeguard against program or patient abuse, to limit the aggregate value of the qualifying electronic prescribing technology that a donor could provide to a physician. We solicited public comment on the applicable amount and methodology for limiting the aggregate value of donated technology.

We also indicated that we were considering setting an initial cap, for both the electronic prescribing and

electronic health records exceptions, which could be lowered after a certain period of time sufficient to promote the initial adoption of the technology. This approach would have the effect of encouraging investments in the desired technology while also ensuring that (as often occurs with technology), as costs decrease and technology becomes more widely adopted, the exception cannot be abused to disguise payments for referrals.

Comment: We solicited public comments that address the retail and nonretail costs (that is, the costs of purchasing from manufacturers, distributors, or other nonretail sources). Only a few commenters provided concrete information on the cost of health information technology, while most commenters simply noted that the cost was high, financial incentives were imperative, and adoption was not equally affordable by all sectors of the health care industry.

Response: We appreciate commenters providing this information, and we have considered this information in finalizing the exception. Again, we note that the Administration supports the adoption of health information technology as a normal cost of doing business to ensure patients receive high quality care.

Comment: Most commenters shared the opinion that there should not be a cap on the value of donated technology, stating that there is not a consistent or appropriate way to determine fair market value or establish a monetary cap that would accommodate all situations and account for the rapid advancement in technology. Some commenters believe that the attempt to ascertain the value of donations for the purpose of fraud protection could become a barrier to adoption of electronic health records, unnecessarily discourage potential donors from providing technology, or result in a reduction on the "return on investment" for electronic prescribing and electronic health records technology. Other commenters expressed concern that a low cap might discourage the implementation of electronic health records technology, while a high cap may serve to pressure hospitals to provide the maximum allowable amount. However, a few commenters shared our concern that allowing donors to provide items or services without limiting the value of such support could provide a potential for program or patient abuse.

One commenter asserted that the value of donations will be self-limiting, because donors are unlikely to spend more than is necessary, thereby eliminating the need for a cap. Another

commenter argued that a cap is not necessary as long as the donation is made without limiting or restricting the use of the electronic prescribing or electronic health records technology to services provided by the donating entity, and as long as the donation does not take into account the volume or value of referrals or other business generated between the parties.

Response: We agree with the commenters that determining the value of donated technology poses certain difficulties and we are not including a cap on the amount of protected donations in the final exception. While gifts of valuable items and services to existing or potential referral sources typically pose a high risk of program or patient abuse, we believe that the combination of conditions in the final exception should adequately safeguard against abusive electronic health records arrangements.

Comment: Most commenters, while opposing the imposition of a cap, offered other suggestions for limiting the value of protected nonmonetary remuneration. Several commenters suggested a limit on the value of protected nonmonetary remuneration in the form of a percentage contribution from the physician, that is, cost sharing by the recipient. These commenters suggested requiring either a set percentage contribution by the physician or a scaled percentage contribution by the physician that would be lowered once a predetermined threshold amount was reached. Some commenters also suggested that we consider a cost sharing method that would be based on set amounts that would be donated, with the physician recipient paying any remaining costs. The amounts could be revised over time to account for the fluctuating expense of technology and other changes that may arise. One commenter noted that studies have shown that individuals value services more when they share a portion of the cost. This commenter suggested that we should require, at a minimum, that physicians contribute towards the purchase of wireless Internet access.

Response: We agree that cost sharing is an appropriate method to address some of the risks inherent in unlimited donations of technology. Accordingly, the exception establishes a contribution percentage that the physician must incur. Specifically, the final rule offers protection under this exception only if the physician pays 15 percent of the donor's cost of the technology. With respect to calculation of the costs, particularly for internally-developed ("homegrown") software (that is, software that is not purchased from an

outside vendor) and internally-developed add-on modules and components (that is, software purchased from an outside vendor and internally customized to ensure operational functionality), parties should use a reasonable and verifiable method for allocating costs and are strongly encouraged to maintain contemporaneous and accurate documentation. Methods of cost allocation will be scrutinized to ensure that they do not inappropriately shift costs in a manner that provides an excess benefit to the physician recipient or results in the physician effectively paying less than 15 percent of the donor's true cost of the technology.

We believe the 15 percent cost sharing requirement is high enough to encourage prudent and robust electronic health records arrangements without imposing a prohibitive financial burden on physicians. Requiring financial participation by a physician should result in selection of technology appropriate for the physician's practice and increase the likelihood that the physician will actually use the technology. Moreover, this approach requires physicians to contribute towards the benefits they may experience from the adoption of interoperable electronic health records (for example, a decrease in practice expenses). We note that, depending on the circumstances, a differential in the amount of cost sharing imposed by a donor on different recipients could give rise to an inference that an arrangement is directly related to the volume or value of referrals or other business generated between the parties, thus, rendering the arrangement ineligible for the protection of the exception. In this regard, the basis for the differential should be closely scrutinized.

We also note that *all* donated software and health information technology and training services are subject to the cost sharing requirements. It is our understanding that many updates and upgrades are included in the initial purchase price of the technology and would not trigger additional cost sharing responsibility on the part of the physician at the time of the update or upgrade. Any updates, upgrades, or modifications to the donated electronic health records system that were not covered under the initial purchase agreement for the donated technology are subject to separate cost sharing obligations by the physician (to the extent that the donor incurs additional costs). To ensure that physician recipients incur the requisite 15 percent of the costs, a donor (and any party related to the donor) is prohibited from

providing financing or making loans to the physician to fund the physician's payment for the technology.

Comment: One commenter stated that we should study the issue of a cap since health information technology capabilities and costs are rapidly evolving.

Response: As noted in the earlier responses, we are not implementing in the final rule a cap on the value of donations of electronic health records technology.

Comment: A few commenters suggested that the final rule should allow donors to reimburse physicians for previously implemented electronic health records systems in an amount equal to the lesser of the fair market value of the donated technology or the cap on the value of donations, should a cap be adopted. These commenters also requested that the donor give assurance to physicians that any technology previously purchased that is equivalent to donated technology and meets the applicable interoperability standards would be integrated into the donor's system.

Response: We are not adopting these suggestions. The commenters' suggestions go beyond the scope of the exception and appear to be a request for the exception to provide retroactive protection for previously purchased technology. The exception protects donations of technology that meet all of the conditions of the exception. The exception does not protect reimbursement for previously incurred expenses, as this would pose a substantial risk of program and patient abuse.

5. Additional Conditions

The proposed rule also listed additional conditions including a restriction on conditioning business on the receipt of electronic health records technology, a requirement that the donor 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-payers requirement, and a requirement that the arrangement not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

Comment: One commenter suggested omitting any requirement that the written agreement documenting the arrangement specify the covered items and services and their values. Another commenter requested clarification as to whether all parties to a three-tier technology arrangement (that is, the donor-distributor of the technology, the

vendor of the technology, and the physician recipient of the technology) would be required to sign the written agreement required by the exception.

Response: In light of the cost sharing condition of the final exception, we are requiring documentation of the cost to the donor of the donated technology, and the physician's contribution to that cost. Moreover, we are requiring that the cost sharing contribution be made and documented *before* the items and services can qualify for protection under the exception. The documentation must be specific as to the items and services donated, the actual cost to the donor, and the amount and confirmation of the physician's cost sharing obligation. The documentation must cover all of the electronic health records items and services to be provided by the donor (or any party related to the donor) to the physician. With respect to this requirement, we have added language to the final exception clarifying that the written documentation requirement can be satisfied by incorporating by reference the agreements between the parties or by the use of cross references to a master list of agreements between the parties that is maintained and updated centrally and is available for review by the Secretary upon request and preserves the historical record of agreements. Nothing in the exception requires that agreements between donors and physicians also be signed by third party vendors; however, such documentation may be a prudent business practice.

Comment: A few commenters suggested that we not sunset the pre-interoperability exception once the post-interoperability exception is finalized, as we had proposed.

Response: We are not finalizing a separate pre-interoperability exception.

Comment: One commenter suggested that the entire electronic health records exception sunset no later than five years from the date of publication of the final rulemaking, with the possibility for the sunset to be delayed upon an administrative finding by the Secretary that there is a still a need for the exception. The commenter observed that, in the future, electronic health records technology will be a standard and necessary part of a medical practice, and there will no longer be a need for third parties to donate it to physicians to spur adoption of the technology. Moreover, the commenter observed that incompatibility across a network of providers will cease to be an issue once interoperability of technology becomes the norm. For these reasons, the commenter concluded that the rationale for establishing an exception to the

physician self-referral law will decrease over time.

Response: We agree with this commenter that the need for an exception for donations of electronic health records technology should diminish substantially over time as the use of such technology becomes a standard and expected part of medical practice. Over time, physicians and others who receive donated technology from third parties may begin to realize the economic benefits from increased efficiencies and quality of care, at which point they should be expected to shoulder the costs associated with producing any benefits. As we indicated earlier in this rulemaking, we are promulgating a physician self-referral exception for the donation of valuable technology to promote its use in the interests of quality of care, patient safety, and health care efficiency, notwithstanding the risk of fraud and abuse normally associated with gifts of valuable goods and services to referral sources. Our goal is to promote the beneficial uses of technology without undue risk of program or patient abuse. As the technology becomes widely used and an accepted part of medical practice, the balance of competing goals underlying the exception changes.

A sunset provision would also address some of our concerns about gifts of unlimited amounts of valuable technology. As noted previously in this final rule, we have concluded that we cannot develop an appropriate cap on the amount of protected technology. A sunset provision, in effect, would cap the amount of protected technology that could be donated by third parties in a different way, thereby safeguarding against program and patient abuse in the long term.

We solicited comments on our overall approach to crafting a set of conditions for the exception and how we might ensure that the conditions, taken as a whole, provide sufficient protection against program and patient abuse. Given the difficulties inherent in limiting the value of donated technology and our relaxing of the ordinary principle that remuneration cannot be linked in any manner to the volume or value of referrals, we believe that the sunset provision suggested by the commenter will provide appropriate additional protection.

For all of these reasons, we are adopting the suggestion of the commenter, with modifications. We are sunsetting the exception on December 31, 2013. This date is consistent with the President's goal of adoption of electronic health records technology by 2014. (See President George W. Bush's

Health Information Technology Plan announced April 26, 2004; http://www.whitehouse.gov/infocus/technology/economic_policy200404/chap3.html.) Under § 411.357(w)(13), all donations of items and services must occur, and all conditions of the exception must have been satisfied, on or before December 31, 2013. Nothing in the exception would preclude the Secretary from extending the time period pursuant to notice and comment rulemaking; we do not believe it would be appropriate to have a condition in a regulation that is contingent on an administrative determination.

We note that we are not similarly sunsetting the electronic prescribing exception at § 411.357(v), as that exception is mandated by statute, and we do not have authority to limit its duration.

Comment: Many commenters supported the prohibition against donors or their agents taking any actions to disable or limit interoperability or otherwise impose barriers to compatibility.

Response: We agree and we are retaining this requirement in the final exception.

D. Summary of the Final Provisions Related to § 411.357(w)

Consistent with the majority of public comments, we have finalized one exception for arrangements involving electronic health records that effectively combines the pre- and post-interoperability proposals. Separate exceptions are no longer necessary, in part, because criteria for product certification are available. Therefore, we have finalized one exception for arrangements involving electronic health records software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records.

The final conditions for the exception, in combination, should promote the important national policy goal of open, interconnected, interoperable electronic health records systems that improve the quality of patient care and efficiency in the delivery of health care to patients, without protecting arrangements that pose a risk of program or patient abuse.

In summary, the final exception includes the following conditions:

- The exception protects arrangements involving nonmonetary remuneration in the form of software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records (provided all conditions of the

exception are satisfied). We have not included hardware. We have clarified that the exception covers "information technology services," including, for example, connectivity and maintenance services. We interpret "training services" to include help desk and other similar support. We have eliminated the language that required the training services to be "directly related" because that language was superfluous in light of the language requiring the training services to be "necessary and used predominantly" for electronic health records purposes.

- We have not adopted the proposal that the protected technology be used solely for electronic health records purposes. Instead, we have included a condition making clear that electronic health records purposes must predominate. Thus, depending on the circumstances, software that relates to patient administration, scheduling functions, billing, clinical support, etc., can be donated. We have also expressly prohibited the provision of any technology used primarily to conduct personal business or business unrelated to the physician's medical practice, as well as the provision of staff to the physician or the physician's office.

To qualify for protection, at the time of donation, the software must be interoperable as defined at § 411.351. Software will be deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the physician. Software must contain electronic prescribing capability (either in an electronic prescribing component or the ability to interface with the physician's existing electronic prescribing system) which complies with the applicable standards under Medicare Part D (the first set of which were promulgated at § 423.160 (see the E-Prescribing and the Prescription Drug Program final rule (70 FR 67568, November 7, 2005)) at the time the items and services are donated. Moreover, the donor (or any agent of the donor) must not take any steps to disable the interoperability of any technology or otherwise impose barriers to the compatibility of the donated technology with other technology.

- The final exception protects broader categories of donors and physician recipients than we proposed. All entities that furnish DHS may make protected donations to *any* physician.

- This final rule clarifies that donors may select physicians for receipt of electronic health records technology using means that do not *directly* take into account the volume or value of

referrals from the physician or other business generated between the parties. The final rule sets forth specific criteria that will be deemed to meet this condition.

- The final rule does not limit the aggregate value of technology that may qualify for protection under this exception. It does contain a requirement that the physician pay 15 percent of the donor's costs. The donor (or any party related to the donor) may not fund any portion of this contribution.
- The final exception adopts the proposed documentation requirements and includes a requirement that the donor's costs be documented in the written agreement between the parties, and permits documentation through incorporation of other agreements between the parties. The final exception does not require that physicians certify that they do not already possess equivalent technology. However, the final exception does preclude protection if the donor knows that the physician already has equivalent technology or acts in deliberate ignorance or reckless disregard of that fact.
- The final exception adopts the proposed conditions related to use of the technology for any patient without regard to payor status and not conditioning business on donations.
- The final exception sunsets on December 31, 2013.

V. Collection of Information Requirements

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 OMB should approve an information collection, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) 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.

Section 411.357 Exceptions to the referral prohibition related to compensation arrangements

We solicited public comments on the information collection requirements listed under § 411.357(v) and § 411.357(w). Section 411.357(v) sets forth the exception for certain arrangements involving the donation of electronic prescribing items and services. Section 411.357(w) sets forth an exception for certain arrangements involving the donation of interoperable electronic health records software or information technology and training services. Specifically, § 411.357(v) addresses the donation of 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. Section 411.357(w) addresses the donation of nonmonetary remuneration (consisting of items or services in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records. For the purposes of this explanation of burden, the items and services discussed in § 411.357(v) and § 411.357(w) will be collectively referred to as "electronic health information technology."

Both § 411.357(v) and § 411.357(w) contain conditions for their respective exceptions. The conditions for both sections require that arrangements for the items and services provided must be set forth in a written agreement that is signed by the involved parties, specifies the items or services being provided and the cost of those items or services (and, in the case of the electronic health records exception, the amount of the physician's contribution), and covers all of the electronic health information technology to be provided by the donor.

The aforementioned requirements associated with these exceptions are limited to donations made to physicians by entities furnishing DHS (for purposes of this Section V and Section VI, "DHS Entities"). We do not know how many DHS Entities will use the exceptions that apply to electronic health information technology. However, we expect that few group practices will use either exception for donations to their members because existing exceptions will likely apply to permit a group practice to provide its physician members with electronic health information technology. In addition, because the donation of electronic health information technology is

voluntary, we believe that some DHS Entities will not avail themselves of this exception and will therefore not experience any paperwork burden.

We expect that every DHS Entity that chooses to provide electronic health information technology to physicians will likely use a model agreement that lists or describes the items and services to be donated. We expect that State or national organizations representing attorneys, physicians, group practices, and DHS Entities will create model agreements for their constituents. We also expect that attorneys for large DHS Entities (for example, academic medical centers or other entities that include hospitals and possibly skilled nursing facilities or home health agencies) will create one model agreement for use by all of their clients that are donors. In addition, we expect a DHS Entity that donates electronic health information technology to create a single model agreement for use for memorializing donations of electronic prescribing and electronic health records technology, because we believe that virtually no donor entity will need or want an agreement that is limited just to the provision of electronic prescribing technology.

The burden associated with these requirements is the time and effort needed to gather the necessary information for the agreement, to draft the agreement, and to review and sign the written document. For donor entities (or their attorneys), we estimate that it will take 1.5 hours to create a model agreement and another 15 minutes to tailor the model agreement for each physician and sign the personalized agreement. Further, we estimate that, on average, each physician will spend 15 minutes reading and signing an agreement, including time spent listening to an explanation from the group practice manager or other physician representative. We recognize that a physician (and a donating entity) will have to understand the differences between the items and services that the donor is offering and the items and services that the physician already possesses or has obtained.

We expect that no more than 150 State or national organizations or attorneys for large hospital systems (or other DHS Entities) will draft agreements for the hospitals and other DHS Entities. Because we estimate it will take 1.5 hours to prepare a model agreement, and 150 different organizations will prepare these agreements, it could take a maximum of 225 hours to prepare all model agreements.

As of April 2006, 609,562 physicians provided Part B physician services to Medicare beneficiaries. To calculate the maximum number of hours required to complete the agreements, we assume that 60,956 physicians (10 percent of the total number of physicians providing Part B physician services to Medicare beneficiaries) will begin the process of developing or using electronic prescribing and/or electronic health records each year. We believe that one-fifth (or 20 percent) of those physicians will accept donations of and sign agreements for electronic health information technology each year. We assume that each of these 12,191 physicians ($60,956 \times 0.20$) will accept two donations of electronic health information technology, and each donation will require that an agreement be signed by the donor DHS Entity and the physician. Each agreement will require 15 minutes (0.25 hours) of the physician's time. Therefore, the physicians might spend 6,096 hours annually in interacting with two donors (2 agreements (that is, 1 per donation) $\times 0.25$ hours for each agreement $\times 12,191$ physicians).

As noted, we expect that a donor entity will spend 15 minutes tailoring and signing each agreement into which it enters. We estimated that 12,191 physicians will enter into 2 agreements each. Therefore, each year, 24,382 agreements will be signed. Each agreement will require 15 minutes (0.25 hours) of the donor entity's time, or 6,096 hours per year ($24,382 \times 0.25$ hours).

We assume that donating entities will not interact with each individual physician, but instead will spend time with individuals or entities that represent physician recipients of donated technology. On average, these representatives represent approximately 25 physicians each. We estimate that a donor entity will spend approximately 2 hours with each physician representative. We estimate that the average yearly burden for donor entities for the interactions with physician representatives may be 975 hours ($[12,191 \text{ physicians}/25 \text{ physicians per representative}] \times 2 \text{ hours per interaction}$). This is in addition to the time spent tailoring and signing physician-specific agreements discussed above.

Assuming that the average cost for the donors and physician recipients involved in this process is \$75 per hour, the annual paperwork burden for the first year should cost \$1,004,400 ($\$75 \times [225 \text{ hours preparing master agreements} + 6,096 \text{ physician hours} + 6,096 \text{ donor hours} + (975 \text{ donor hours spent with$

group practice or physician representatives $\times 2$ agreements per physician)]) with each additional future year costing \$987,525 ($\$75 \times [6,096 \text{ physician hours} + 6,096 \text{ donor hours} + (975 \text{ donor hours spent with group practice or physician representatives} \times 2 \text{ agreements per physician}])$).

An additional requirement for both exceptions will be that of maintaining the written agreements required to comply with § 411.357(v) and § 411.357(w), and, if necessary, making them available to the Secretary upon request. We are requiring entities to maintain information that they already maintain as part of their usual and customary business practices. In addition, the information would only be collected during the conduct of an administrative action, investigation, or audit involving a Federal governmental agency regarding specific individuals or entities.

We believe that the recordkeeping requirements in this section are exempt from the PRA under both 5 CFR 1320.3(a)(2) and 5 CFR 1320.4(a)(2).

These requirements are not effective until they are approved by OMB.

VI. Regulatory Impact Analysis

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 will have an annual effect on the economy of \$100 million or more in any one year, or will 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 final rule

will 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 responses that have helped us make final decisions.

This final rule creates two new exceptions to the physician self-referral prohibition. The first exception permits certain entities to provide to physicians hardware, software, or information technology and training services necessary and used solely to receive and transmit electronic prescription information, provided that certain conditions are satisfied. The second exception permits DHS Entities to provide to physicians software and information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records, provided that certain conditions are satisfied. (Electronic prescribing technology and electronic health records technology are collectively referred to as "electronic health information technology" for purposes of this Section VI.)

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 contribute toward all of the health information technology used by physicians.

Recently, *Modern Healthcare* presented findings from its annual survey (conducted in December 2005 through early January 2006) of 601 health care executives regarding whether respondents (about 80 percent of which were hospitals or health care systems that include hospitals) would be willing to contribute to physician office health information technology if the physician self-referral provisions and the anti-kickback statute did not prohibit such donations. The findings showed that 70.2 percent of respondents would be willing to allocate money to help a referring physician buy and use clinical information technology (up from 59 percent last year). Table 1 shows the breakdown percentages of respondents that would be willing to subsidize varying amounts of the startup costs for computerizing physicians' practices.

TABLE 1

Percentage of all respondents	Percentage of startup costs respondents would be willing to subsidize
29.80	no amount
32.36	20 percent or less
8.77	21–40 percent
15.16	41–60 percent
4.28	61–80 percent
9.69	81–100 percent

This survey indicates that, as of the beginning of calendar year 2006, over 60 percent of the CEOs surveyed did not see their institutions providing more than 20 percent of the costs necessary to initiate the computerization of physician offices for the purpose of clinical information technology. (Conn, Joseph, "Subsidies: Ready to give, but * * *," *Modern Healthcare*, S5, February 13, 2006). Interestingly, this same survey showed that 65.1 percent of the executives indicated that moving toward an electronic health record was one of their top 10 information technology priorities, whereas only 51.6 percent chose "improve patient-care capabilities." (Conn, Joseph, "EHRs: Still in hot pursuit," *Modern Healthcare*, S1, February 13, 2006). However, 42.1 percent of the surveyed executives indicated that they expected their organizations to spend approximately 1.6 percent to 3.0 percent of their total operating budget on information systems. Nearly 21 percent of the executives predicted that their organizations would spend less than 1.6 percent, and 37.3 percent predicted that their organizations would spend more than 3.0 percent of their total operating budget on information systems. (Conn, Joseph, "Budgets: Opening the wallet," *Modern Healthcare*, S2, February 13, 2006).

We believe that health care entities are waiting for the completion of a sizeable number of national standards before committing substantially for electronic health records items and services, first for themselves, and then for physicians and other entities in their communities.

The final rule establishing the first set of standards for electronic prescribing in the Part D program, which was published on November 7, 2005 (70 FR 67568), discusses 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. 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 DHS Entities will find it in their interest to pay some or all of the costs of qualifying health information technology to encourage physician adoption of such technology.

This final rule removes a potential obstacle to the provision of qualifying health information technology by certain entities. This final rule applies to donations of qualifying health information technology by DHS Entities, and we expect that many donor entities may not need to use these exceptions, given the existing provisions at § 411.352 for group practices and the exception at § 411.355(c) for managed care services. (See 66 FR 856 and 69 FR 16054.) 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 (incentives that are larger than those for most other entities) to encourage the adoption of health information technology by contracting physicians.

Regardless of whether donations are allowed under existing exceptions or those that are included in this final rule, we encouraged commenters to provide information on the costs that likely will be incurred by entities that choose to provide qualifying health information technology to physicians, as well as other related costs that likely will 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 final rule is restricted by the potential effects of outside factors, such as technological progress and other market forces, future certification standards, and companion final anti-kickback statute safe harbors. Furthermore, both the costs and potential savings of electronic prescribing, electronic health records, and administrative software such as billing and scheduling vary to the extent to which each element operates as a stand-alone system or as part of an integrated system. We solicited comments to help identify both the independent and synergistic effects of these variables.

As discussed in the November 7, 2005 E-Prescribing final rule (70 FR 67584 through 67588), donors may experience net savings with electronic prescribing in place, and patients will experience

significant positive health effects. We have not repeated that analysis in this final 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—

- 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," *American Journal Medicine* 106(2), 144–50 (1999)); (Tierney, W., et al., "The effect on test ordering of informing physicians of the charges for outpatient diagnostic tests," *New England Journal of Medicine* 322(21): 1499–504 (1990)); (Tierney, W., et al., "Computerized display of past test results. Effect on outpatient testing," *Annals Internal Medicine* 107(4): 569–74 (1987));

- 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));

- 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," *Pharmacoeconomics and Drug Safety* 10(2), 113–19 (2001)); and

- Reducing excess medication usage by 11 percent (Wang, S., et al., "A cost-benefit analysis of electronic medical records in primary care," *American Journal of Medicine* 114(5): 397–403 (2003)); (Teich, J., et al., "Effects of computerized physician order entry on prescribing practices," *Archives of Internal Medicine* 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," *Effective Clinical Practice* 1(2): 73–82 (1998)).

These studies show a consistent pattern of reductions in clinical utilization reported to arise from electronic health records use in ambulatory settings. Although financial estimates were not performed in these studies, these reductions in utilization could yield savings that accrue to the Medicare program because of its high volume of payments for ambulatory and inpatient care. Other studies have

estimated that electronic health records in the ambulatory setting will 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 substantial.

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.).

HealthLeadersMedia interviewed individuals from 5 medical practices to try to determine reasons (other than money) for the fact that, as of 2005, only 14 percent of physician groups used database-driven electronic health records systems. One sole practitioner put \$70,000 into hardware and software to duplicate the system she had used when in a group practice. Although this physician reduced much of the external paper flood, she has not saved money. She replaced transcription costs with

scanning expenses. This physician is pleased that she can document more detail electronically than by hand, resulting in more appropriate reimbursement. A small rural clinic hired a vendor after a year's search, but then endured multiple delays and missed deadlines. After firing its vendor, it hired another vendor with a similar lack of results. Finally, it hired a vendor that the rural health clinic had interviewed two years earlier after discovering that this vendor had significantly upgraded its clinical documentation system, and the rural health clinic is now satisfied. On the other hand, a physician practice with over 500 physicians reported that, because it spent a lot of time in design, workflow analysis, and early development before employing any system, it is very satisfied with its physician-friendly system. Another physician practice, with five physician members, successfully adopted information technology with its third contractor resulting in financial and clinical benefits, including running the practice much more efficiently which resulted in treating more patients. Finally, a group practice with 13 internists borrowed \$600,000 for hardware and software for an electronic health records system. Annual transcription costs have decreased from \$150,000 to \$30,000 and records are easily shared. (Baldwin, Gary, "Paper Charts No More," <http://www.healthleadersmedia.com> (May 2006)).

Another recent study reviewed a broader range of providers and argued 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 in this section, 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. Even so, a recent survey by the Center for Studying Health System Change indicated that between 2000–2001 and 2004–2005, the proportion of physicians in their own practices reporting access to information technology for treatment guidelines increased from 52.9 percent to 64.8 percent, and the number of electronically prescribing physicians increased from 11.4 percent to 21.9 percent. In addition, the percent of physicians in practices who reported that they had used information technology to exchange clinical data increased from 40.6 percent to 50.1 percent during this time period. (Reed, Marie C. and Grossman, Joy M., "Growing Availability of Clinical Information Technology in Physician Practices," Data Bulletin No. 31, Center for Studying Health System Change, <http://www.hschange.com> (June 2006)).

The major barriers to physician adoption of clinical information technology include start-up and maintenance costs, and the significant effort and costs of changing workflow to use information technology effectively. (Bates, David W., "Physicians and Ambulatory Electronic Records," *Health Affairs*, (September/October 2005)). However, in an interview, Joy Grossman of the Center for Studying Health System Change, cited above, indicated her belief that one reason for the delay in physician adoption of information technology is that physicians want to make sure that the type of technology and software they purchase will not become obsolete and also will be compatible with tools used by hospitals, other physicians, and health plans. (Agovino, Theresa, "Doctor Access to Information Technology Up," the Associated Press, reported by the Houston Chronicle at <http://www.chron.com> (June 6, 2006)).

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 this final rule is: taking into account available policy instruments (notably the development of interoperability standards), to what extent does the use of these physician self-referral exceptions accelerate adoption of electronic prescribing and electronic health records technology?

We do not have good baseline information. There are numerous estimates for the adoption rate 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 while others do not. 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, both of these percentages fall to 10 percent. (See Gans, D., *supra.*)

As discussed in this section, we estimate that 2 percent of physicians and an unknown number of DHS Entities will be affected by these exceptions each year. Put another way, only one in five physicians adopting electronic health information technology will utilize these exceptions annually.

As explained in the November 7, 2005 E-Prescribing final rule (70 FR 67585), 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. We believe it is likely that about one in five of those prescribers will receive assistance under these exceptions. (Another one in five will 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 DHS Entities as to whether to provide assistance to physicians for electronic health information technology and the decisions of physicians and group practices to implement these systems. We solicited information about the intentions of DHS Entities to make donations of qualifying health information technology to physicians and the willingness of physicians and 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 will 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 electronic health information technology that a physician will need from a donor.

Although we do not know the cost of the electronic health information technology, we describe below several studies of the costs and benefits of equipping doctors with such technology. The speed of adoption depends on the extent to which physicians realize net benefits (discussed extensively in the proposed rule) and on the extent to which our exceptions incrementally affect the costs and savings of the technology.

One study of data on the costs associated with an internally-developed electronic health records system for several internal medicine clinics in 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; the maintenance of 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 health 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 Records 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. The 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, 9-location group practice, installed an electronic health records system in April 2002. (Barlow, S., *et al.*, "The Economic Effect of Implementing an EMR in an Outpatient Clinical Setting," *Journal 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 improved documentation. (This study did not include information about the start-up or annual costs of the electronic health records system. 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"¹ 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.

The following are our responses to comments to the Regulatory Impact Analysis in the proposed rule:

Comment: One commenter asserted that the estimate that we used in the proposed rule for the cost of information technology items and services is too low. Another commenter estimated that electronic health records systems cost between \$700 and \$800 per physician per month during the first 5 years of implementation. A third commenter estimated that the implementation cost for each physician will range from \$15,000 to \$35,000. Another commenter asserted that donors will probably donate approximately \$5,000 per physician and that no donor will provide items and services worth over \$35,000 per physician. One commenter agreed that donations will result in a reduction of the utilization of unneeded

¹ 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."

health care services. Finally, a commenter agreed that there should not be a significant impact on small businesses.

Response: We recognize that the cost of implementing information technology in the physician office setting currently appears to be substantial, with benefits that will be recognized, but not immediately. Recently, Robert Miller and colleagues at the University of California, San Francisco, presented findings from case studies of 14 sole practitioners and small group practices in twelve States. They found that start-up costs average \$44,000 per physician and annual maintenance costs average \$8,400 per physician per year. However, they also found that the physicians recoup their investment costs in 2.5 years, with over half of the financial benefits coming from improved billing services. In addition, physician practice revenues increased by \$17,000 per year and efficiency savings and gains from greater physician productivity averaged \$15,800 per physician per year. (Miller, Robert H., et al., "The Value of Electronic Health Records in Solo or Small Group Practices, *Health Affairs*, September/October 2005.)

We presented information above in this section from a recent *Modern Healthcare* survey that indicated a breakdown of the funding that 501 health care executives anticipated that their institutions will spend to help physician practices with information technology. (Conn, Joseph, "Subsidies: Ready to give, but * * *," *Modern Healthcare*, S5, February 13, 2006). The figures in that article are not considerably different from the commenter's estimates.

Comment: One commenter believes that donors will be concerned about the direct impact to their patient populations and the common good.

Response: We hope that donors will recognize that physicians need systems that will work for their patients and practices. We believe that the studies we have cited indicate the importance of physicians being able to use the systems they are purchasing and implementing. If a system does not work for a physician, he or she will abandon the system.

We believe that donations protected under this exception will create no net costs to the economy. This rule will permit cost-shifting, allowing DHS Entities 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 in a timely manner should benefit patients, physicians, and DHS Entities. The November 7, 2005 E-Prescribing final rule (70 FR 67586) cites an estimate from the CITL that nationwide adoption of electronic prescribing will eliminate nearly 2.1 million ADEs per year. In turn, this reduction of ADEs will prevent nearly 1.3 million provider visits, more than 190,000 hospitalizations, and more than 136,000 life-threatening ADEs. We hope to see a significant reduction in ADEs each year as nationwide adoption of electronic health information technology occurs.

We estimate that 10 percent of the 609,562 physicians who provide Part B services to Medicare beneficiaries (60,956 physicians) will adopt electronic prescribing and electronic health records technology each year. We believe it is likely that DHS Entities will donate software or other items or services to no more than one-fifth (or 20 percent) of these physicians (or to fewer than 12,191 physicians) under these exceptions, and perhaps another one-fifth (or 20 percent) of these physicians (again fewer than 12,191 physicians) will receive donations under the existing exceptions that apply to managed care services and to group practices. We estimate that, at most, each physician will receive a total of \$3,000 worth of donated items and services per donation under the exceptions. Therefore, assuming that 2 percent of physicians (1/5 of the 10 percent of physicians adopting the technology per year) will receive \$3,000 worth of donated electronic health information technology, annual donations approximate \$36 million.

We expect that many physicians already own handheld devices and will have begun to computerize their own medical practices. We also expect that DHS Entities will see immediate benefits from the expanded use of electronic prescribing and electronic health records technology. We anticipate that these savings will be greater than the costs incurred by donor entities using these exceptions, but we cannot quantify the savings at this time.

We note that a significant benefit of electronic health records was recognized in 2005. 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 <http://www1.va.gov/opa/pressrel/pressrelease.cfm?id=1152>).

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 Ochsner Clinic in New Orleans had also computerized its patient records prior to Hurricane Katrina and, thus, was able to recover its practice after the hurricane.

The estimates above are highly sensitive to assumptions. The cost to the donor for the donated items and services might be significantly higher or lower than discussed above. The rate of adoption may be higher or lower than estimated. The proportion of physicians receiving remuneration could be higher or lower than estimated, depending on the willingness of DHS Entities to subsidize investment in health information technology.

We also note that, 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 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 will 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 will 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 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.

Finally, we believe it unlikely that annual effects will 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 final rule is not a major rule. However, we have completed all the elements of a RIA 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 final rule imposes no mandates. Any actions taken under this rule are voluntary. Furthermore, such actions are likely to result in net cost savings, not net expenditures. Any expenditure undertaken by government-owned hospitals in their business capacity will not necessarily have an 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 issues a 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 final rule will not have a substantial effect on State or local governments, nor does it preempt State law or have Federalism implications.

B. Impact on Small Businesses

The RFA requires agencies to analyze options for regulatory relief for small entities when a final 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 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 final rule will not have a financial impact on small governmental entities.

We have determined that this final rule will 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 may be substantial, it is unlikely that near term effects on individual practitioners will be substantial as a proportion of revenues (for example, neither a \$3,000 donation nor a \$450 cost sharing contribution (15 percent of

\$3,000) is significant compared to typical practice revenues in the hundreds of thousands of dollars). We expect our new exceptions ultimately to be highly beneficial to physicians and DHS Entities (most in both categories 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.

Nothing in this final 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 final rule will not have a significant economic effect. Although the final 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 will 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 will remove a potential obstacle to certain entities providing electronic prescribing and electronic health records technology and services to physicians. The rule will permit cost shifting, allowing DHS Entities 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 and DHS Entities.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will 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 amends 42 CFR chapter IV part 411 as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 1. The authority citation for part 411 is revised to read as follows:

Authority: Secs. 1102, 1860D–4(e)(6), 1871, and 1877(b)(4) and (5) of the Social Security Act (42 U.S.C. 1302, 1395w–104(e)(6), 1395hh, and 1395nn(b)(4) and (5)).

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

■ 2. Section 411.351 is amended by adding the definitions of "electronic health record" and "interoperable" in alphabetical order to read as follows:

§ 411.351 Definitions.

* * * * *

Electronic health record means a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.

* * * * *

Interoperable means able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.

* * * * *

■ 3. Section 411.357 is amended by adding paragraphs (v) and (w) to read as follows:

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

* * * * *

(v) *Electronic prescribing items and services.* 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 by a—

(i) Hospital to a physician who is a member of its medical staff;

(ii) Group practice (as defined at § 411.352) to a physician who is a member of the group (as defined at § 411.351); or

(iii) PDP sponsor or MA organization to a prescribing physician.

(2) The items and services are provided 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 provided.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records 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 does 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, or the amount or nature of the 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 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 and services being provided and the donor's cost of the items and services; and

(iii) Covers all of the electronic prescribing items and services to be provided by the donor. This requirement will be met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list should be maintained in a manner that preserves the historical record of agreements.

(8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.

(w) *Electronic health records items and services.* Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records, if all of the following conditions are met:

(1) The items and services are provided by an entity (as defined at § 411.351) to a physician.

(2) The software is interoperable (as defined at § 411.351) at the time it is provided to the physician. For purposes of this paragraph, software is deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the physician.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility or interoperability of the items or services with other electronic prescribing or electronic health records systems.

(4) Before receipt of the items and services, the physician pays 15 percent of the donor's cost for the items and services. The donor (or any party related to the donor) does not finance the physician's payment or loan funds to be used by the physician to pay for the items and services.

(5) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the 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 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. For purposes of this paragraph, the determination is deemed not to directly take into account 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 physician (but not the volume or value of prescriptions dispensed or paid by the donor or billed to the program);

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

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

(iv) The determination is based on the physician'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 donor's medical staff, if the donor has a formal medical staff;

(vi) The determination is based on the level of uncompensated care provided by the physician; or

(vii) The determination is made in any reasonable and verifiable manner that does not directly take 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 and services being provided, the donor's cost of the items and services, and the amount of the physician's contribution; and

(iii) Covers all of the electronic health records items and services to be provided by the donor. This requirement will be met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list should be maintained in a manner that preserves the historical record of agreements.

(8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.

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

(10) The items and services do not include staffing of physician offices and are not used primarily to conduct personal business or business unrelated to the physician's medical practice.

(11) The electronic health records software contains electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the physician's existing electronic prescribing system that meets the applicable standards under Medicare Part D at the time the items and services are provided.

(12) 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.

(13) The transfer of the items or services occurs and all conditions in

this paragraph (w) are satisfied on or before December 31, 2013.

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

Dated: June 28, 2006.

Mark B. McClellan,
Administrator, Centers for Medicare & Medicaid Services.

Approved: July 14, 2006.

Michael O. Leavitt,
Secretary.

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