Supporting Statement – Center for Medicare and Medicaid Services
Physician Self-Referral Exceptions for Electronic Prescribing and Electronic Health Records -- Final Rule (CMS-1303-F)

A. Background

Section 1877 of the Social Security Act (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 the physician (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 payer for those referred services, unless an exception applies. The statute establishes a number of exceptions and grants the Secretary of the Department of Health and Human Services (HHS) authority to create additional regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

B. Justification

1. Need and Legal Basis

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directs the Secretary to create an exception to the physician self-referral prohibition in section 1877 of 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.

The conditions for both exceptions require that arrangements for the items and services provided must be set forth in a written agreement, be signed by the parties involved, specify the items or services being provided and the cost of those items or services, and cover all of the electronic prescribing and/or electronic health records technology to be provided by the donating entity. We have suggested that, instead of one master agreement that is updated with each new donation, the parties may choose to create a specific new contract and then reference other agreements or cross-reference a master list of agreements.

The requirements associated with the exception for electronic prescribing items and services are limited to donations made by hospitals to members of their medical staffs; by group practices to their physician members; and by PDP sponsors and MA organizations to prescribing physicians. The requirements associated with the exception for electronic health records software or information technology and training services include donations by entities furnishing DHS to physicians. The paperwork burden is the creation and execution of the written agreements. The burden associated with the written agreement requirement is the time and effort necessary for documentation of the agreement between the parties, including the signatures of the parties.

2. Information Users

CMS would use the collected information for enforcement purposes. Specifically, if we were investigating the financial relationships between the donors and the physicians to determine whether the provisions in the exceptions at §§ 411.357 (v) and (w) were met, first, we would review the written agreements that indicate what items and services each entity intended to provide.

3. Use of Information Technology

We believe that the use of information technology will keep the recordkeeping burden relatively low because an attorney will be able create a model agreement on a computer that may be used repeatedly with minor changes to describe the items and services being donated. The attorney's clients may then use the computerized document to add the provisions of each new agreement to a master list of agreements or to modify the master agreement. However, the collection requires a signature from both the donor and the physician to whom the donation is made. Electronic signatures may be appropriate. We are interested in encouraging electronic agreements.

4. Duplication of Similar Information

The information to be created does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Business

These information collection requirements do not impact small businesses.

6. Less Frequent Collection

Because the agreement memorializes the items or services that a provider is donating, there could not be less frequent collection.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on May 25, 2007.

On October 11, 2005, we published a proposed rule to create exceptions to the physician self-referral law for arrangements involving electronic prescribing and electronic health records technology (70 FR 59182). 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 exceptions.

We have not included any certification requirements in the final rule. We agree that a combination of agreements may satisfy the documentation requirement.

9. Payment/Gift to Respondents

There will be no payment or gifts to respondents.

10. Confidentiality

If we need to review the agreements, we are prevented by the Trade Secrets Act, 18 U.S.C. § 1905, from releasing to the public confidential business information, except to the extent permitted by law. We intend to protect from public disclosure, to the fullest extent permitted by Exemption 6 of the Freedom of Information Act, 5 U.S.C. § 552(b)(6), any individual-specific information that we review.

11. Sensitive Questions

The written agreements will contain no sensitive questions, such as sexual behavior and attitudes, religious beliefs, and other matters that we commonly consider private.

12. Burden Estimate (Hours & Wages)

We expect that no more than 150 State or national organizations or attorneys for large hospital systems and other DHS entities will draft model agreements. 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 December 2006, 655,995 physicians provided Part B physician services to Medicare beneficiaries. To calculate the maximum number of hours required to complete the agreements, we assume that 65,600 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. Of those physicians, we expect that one-fifth (or 20 percent) will accept donations of and sign agreements for electronic health information technology each year. We assume that each of those 13,120 physicians 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 (.25 hours) of the physician's time. Therefore, the physicians might spend 6,560 hours annually in interacting with two donors (2 agreements (that is, 1 per donation) X .25 hours for each agreement X 13,120 physicians) and the donors will spend an equivalent amount of time as the physicians (6,560 hours annually).

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 1,050 hours ([13,120 physicians/25 physicians per representative] X 2 hours per interaction). Each physician representative will spend time with 2 donors so that yearly burden will be 2,100 hours. ([13,120 physicians/25 physicians] X 2 hours per interaction X 2 interactions). This is in addition to the time spent tailoring and signing physician-specific agreements discussed above. The same number of donors will spend the same amount of time as the physician representatives or 2,100 hours interacting with physicians.

Assuming that the average cost for the donors and physician recipients involved in this process is $77.55 per hour [$75 (2006 cost per hour X 103.4 percent (to take account of the increase in the Employment Cost Index for Professional and Related Index calculated by the Bureau of Labor Statistics))], the annual paperwork burden for the next year should cost $1,360,614.70 ($77.55 X 17,545) which results from 225 hours preparing master agreements + 8,660 physician hours + 8,660 donor hours. Each additional future year should cost $1,343,166 ($77.55 X [8,660 physician hours + 8,660 donor hours]).

13. Capital Costs

There are no capital costs required for this data collection.

14. Cost to the Federal Government

There are no additional costs to the Federal government.

15. Program/Burden Changes

The burden increased due to an increase in the number of providers.

16. Publication and Tabulation Duties

None.

17. Expiration Date

December 31, 2013.

18. Certification Statement

No exceptions.

C. Collections of Information Employing Statistical Methods

This section is not applicable.