Supporting Statement – Center for Medicare and Medicaid Services
Extension of 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) directed 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, CMS created 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.

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. The parties may choose to create a specific new contract and then reference other agreements or cross-reference a master list of agreements, rather than maintain one master document.

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

A 60 day Federal Register notice published on September 10, 2010. No comments were received.

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 and Wages)

We believe that many State or national organizations or attorneys for large hospital systems and other DHS entities have already drafted model agreements during the past several years that these exceptions have been in effect. We also expect that, due to the incentive payment programs related to adoption of electronic health records technology, new organizations will continue to draft model agreements. We expect that 75 new State or national organizations or attorneys for large hospital systems and other DHS entities will draft model agreements each year. Because we estimate it will take 1.5 hours to prepare a model agreement, and 75 different organizations will prepare these agreements, it could take a maximum of 112.5 hours to prepare all model agreements.

As of July, 2007 there are 667,340 physicians providing Part B physician services to Medicare beneficiaries according to the 2009 CMS Statistics booklet. According to the Office of the National Coordinator for Health IT (ONC), nearly 200,000 physicians have already adopted electronic health records technology. Of the remaining 467,340 physicians providing Part B services to Medicare beneficiaries, we assume that 46,734 physicians (10 percent of the total number of physicians providing Part B physician services to Medicare beneficiaries who have not yet adopted health records technology) 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 9,347 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 4,673.5 hours annually in interacting with two donors (2 agreements (that is, 1 per

donation) X .25 hours for each agreement X 9,347 physicians) and the donors will spend an equivalent amount of time as the physicians (4,673.5 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 748 hours ([9,347 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 1,496 hours. ([9,347 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 1,496 hours interacting with physicians.

Assuming that the average cost for the donors and physician recipients involved in this process is $83.59 per hour according to the average hourly rate reported by the Bureau of Labor Statistics, the annual paperwork burden each year should cost $1,040,820.89 ($83.59 X 12,451.5) which results from 112.5 hours preparing master agreements + 6,169.5 physician hours + 6,169.5 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 annual burden hours decreased due to fewer providers drafting original agreements and the decrease in the annual number of responses is due to a reduced number of providers adopting this technology because many already have.

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.