Supporting Statement Part A
Extension of Physician Self-Referral Exceptions for Electronic Prescribing and Electronic Health Records
CMS-10207, OCN 0938-1009

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.

A. 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

The 60-day Federal Register notice published on June 28, 2013 (78 FR 40482). 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 annually, it could take a maximum of 112.5 hours to prepare all model agreements. We expect the lawyers will prepare these model agreements. According to the average hourly rate of $54.58, reported by the Bureau of Labor Statistics, the cost per response to the state and national organizations will be $81.67. The annual cost to state and national organizations will be (113 hours x 75) $8,475.00.

As of June, 2010, there are 616,749 physicians providing Part B physician services to Medicare beneficiaries according to the 2010 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 416,749 physicians providing Part B services to Medicare beneficiaries, we assume that 41,675 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 8,335 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 4,167.5 hours annually on interacting with two donors (2 agreements for each of the 8335 physicians (that is, 1 per donation) X .25 hours for each agreement X 16670 (8335 physicians X 2) and the donors will spend an equivalent amount of time as the physicians (4,167.5 hours annually). The average hourly rate for physicians is of $86.75, according to the Bureau of Labor Statistics. The hourly cost to physicians is $21.69 (86.75 X .25). The annual cost to physicians will be (4,167.5 hours x 21.69) $90,382.23.

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 666 hours ([8,335 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 1,332 hours. ([8,335 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 1,332 hours interacting with physicians. The average hourly rate for physician representatives is of $13.36, according to the Bureau of Labor Statistics. The hourly cost associated with physician representatives is $26.72(13.36 X 2). The annual cost associated with physician representatives is (1,332 hours x 26.72) $35,591.04.

We assume that there are 333 donating entities providing electronic health record technology to physicians. We assume that donating entities will interact with physicians for .25 hours. Additionally, we estimate that a donor entity will spend approximately 2 hours with each physician representative. Therefore, we estimate the hourly burden to donors to be 2.25 hours. We expect the donors to interact twice with each of the 8335 physicians and their representatives. We estimate that the average yearly hourly burden for donor entities for the interactions with physician representatives may be 750 hours ([8,335 physicians/25 physicians per representative] X 2.25 hours per interaction). The average hourly rate for donors (general business and operations mangers) is of $55.22, according to the Bureau of Labor Statistics. The hourly cost associated with physician representatives is $138.05(55.22 X 2.5). The annual cost associated with physician representatives is (750 hours x 138.05) $103,537.50.

HOUR BURDEN

Respondent	Total Number of Responses	Hours per response	Annual Burden	Rounded Hour Totals
75 State or National Organizations	75	1.5	112.5	**113**
8335 Physicians	16670	.25	4167.5	**4,168**
333 Donors	333	2.5	750	**750**
333 Physician Representatives (8335/25)	666	2	1,332	**1,332**
Totals	**17,744**			**6,363**

COST BURDEN

Respondent	Total Number of Responses	Cost per response	Annual Burden	Rounded Cost Totals
75 State or National Organizations	75	81.67	8,475.00	**8,475.00**
8335 Physicians	8335	.25	90,382	**90,382**
333 Donors	333	2.5	103538	**103,538**
333 Physician Representatives (8335/25)	666	2	35,591	**35,591**
Totals	**9,409**			**237,986**

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 has decreased and has been adjusted to account for fewer providers drafting original agreements. The annual number of responses has also decreased and has been adjusted to account for the reduced number of providers adopting this technology because many already have this in place.

16. Publication and Tabulation Duties

None.

17. Expiration Date

Displaying the expiration date is not applicable to this PRA package.

18. Certification Statement

No exceptions.

B. Collections of Information Employing Statistical Methods

Not applicable.