Supporting Statement – Part A
Section 6003 of the ACA: Disclosure Requirements for In-office Ancillary Services Exception to the Prohibition on Physician Self-referral for Certain Imaging Services

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 to the prohibition of physician self-referral.

Section 6003 of the Affordable Care Act created a new disclosure requirement for the in-office ancillary services exception to the prohibition of physician self-referral for certain imaging services. The statute amends section 1877(b)(2) of the Act by adding a requirement that the referring physician informs the patient, at the time of the referral and in writing, that the patient may receive the imaging service from another supplier. The imaging services affected by this new requirement are: magnetic resonance imaging, computed tomography, and positron emission tomography. We amended 42 CFR §411.355(b) with a new paragraph (7) describing the new requirements. The physician must disclose to the patient that the services may be obtained from another supplier and also provide a list of other suppliers that provide the same imaging services.

B. Justification

1 . Need and Legal Basis

In recent years there has been an increased interest in physician self-referral in certain areas of medicine. One area that has received attention is advanced imaging (MRI, CT, PET). Congress has implemented a new requirement to assist patients in making informed decisions regarding their care and to also possibly curb abusive physician self-referral for these services.

Section 6003 of the Affordable Care Act created a new disclosure requirement for the in-office ancillary services exception to the prohibition of physician self-referral for certain imaging services. The statute amends section 1877(b)(2) of the Social Security Act by adding a requirement that the referring physician informs the patient, at the time of the referral and in writing, that the patient may receive the imaging service from another supplier. We amended 42 CFR §411.355(b) with the new requirements.

2. Information Users

Physicians who provide certain imaging services (magnetic resonance imaging, computed tomography, and positron emission tomography) under the in-office ancillary services exception to the physician self-referral prohibition will be required to create the disclosure notice as well as the list of other imaging suppliers to be provided to the patient. The patient will then be able to use the disclosure notice and list of suppliers in making an informed decision about his or her course of care for the imaging service.

CMS will use the collected information for enforcement purposes. Specifically, if we were investigating the referrals of a physician providing advanced imaging services under the in-office ancillary services exception, we would review the written disclosure in order to determine if it satisfied the requirement.

3. Use of Information Technology

The information is created by the physician or group practice and then communicated to the patient. We believe that gathering the list of suppliers to be provided to the patient will be conducted primarily electronically, via the internet. Once a record of the physician and patient's signatures are obtained, this may be converted into a part of an electronic medical chart, depending on the technology used by the physician's practice.

CMS is not collecting this information at this time, so it cannot be collected electronically by the Agency.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source as this disclosure requirement had not previously existed.

5. Small Businesses

These information collection requirements do not impact small businesses.

6. Less Frequent Collection

This information will be distributed to patients as the imaging services are ordered. There is no other way to change the frequency with which this information must be communicated.

7. Special Circumstances

The disclosure requirement does not have an end date. Currently, this is a statutory requirement for the in-office ancillary services exception that will be applied on an ongoing basis.

8. Federal Register/Outside Consultation

This proposal was published in a notice of proposed rulemaking in order to afford the public

adequate time to respond in the form of public comments. The proposed rule provided a 60-day comment period and the final rule provided a 30-day comment period. The PRA requirement of the notice appeared at 75 FR 40224.

9. Payments/Gifts to Respondents

There will be no payment or gifts to respondents.

10. Confidentiality

CMS pledges to maintain privacy to the extent provided by law. 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 Estimates (Hours & Wages)

We expect that this requirement will affect only those physicians who provide MRI, CT, PET services under the in-office ancillary services exception. We are uncertain of the number of physicians who will have to comply with this disclosure requirement. Using data from the 2009 CMS Statistics booklet, we propose an estimate of 71,000 Medicare enrolled physicians would have to comply with this new requirement. This figure represents 20% of primary care and medical specialty physicians enrolled in Medicare Part B. The number of physicians who have to create a unique disclosure document may be lower than this because physicians practicing in a group practice at the same location will be able to use the same disclosure document once created.

In response to public comments received we have decreased the number of suppliers that must be listed in the disclosure notice from 10 to 5. Our estimate remains the same that it will take an employee of the physician 1 hour to create the initial disclosure form one time. The average payment rate for this type of employee, a healthcare support worker in a physician office, is $14.68 according to the Bureau of Labor Statistics. If each physician who will have to make this disclosure has a form created, the annual cost burden of creating the disclosure and list of alternative suppliers is $1,042,280.00 (1 hour x $14.68 x 71,000 physicians). The annual burden hours for creating the disclosure forms the first year will be 71,000 hours.

In the final rule with comment period, we have removed the requirement that a physician obtain the patient's signature on the disclosure notice and maintain a copy of this in the

medical record. Without the signature requirement, we estimate that it will take physicians 1 minute to provide the disclosure to the patient and to document that the disclosure was given to the patient by whatever means the physician chooses. The average hourly rate for a general practice physician in a physician office, according to the Bureau of Labor Statistics, is $83.79. The annual burden for the actual disclosure by the physician is estimated to be $10,536,400. We calculated this amount by using data in the CMS 5% carrier standard analytic file using data from 2008. The number of advanced imaging services performed by specialties other than radiology or IDTFs in 2008 was 7,545,760. We took this total number of services and divided it by the total number of physicians affected by this provision, 71,000 and determined that a physician will make approximately 106 disclosures a year. The annual cost burden for this provision was calculated by taking 106 disclosures per year per physician x $1.40 per disclosure = $148.40 a year per physician x 71,000 physicians = $10,536,400.

The estimated annual hour burden for this disclosure requirement is 125,433 hours for all affected physicians. To calculate the total burden hours we multiplied 106 disclosures annually per physician x 71,000 physicians x 1 minute (1/60) = 125,433 hours a year for all disclosures.

13. Capital Costs

There are no capital costs related to this collection.

14. Cost to Federal Government

There are no additional costs to the federal government.

15. Changes to Burden

No changes to the burden.

16. Publication/Tabulation Dates

The results of this collection of information will not be published.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

No exceptions.