Supporting Statement – Part A

(0938-0968)

Supporting Statement For Paperwork Reduction Act Submissions

General Instructions

A Supporting Statement, including the text of the notice to the public required by 5 CFR 1320.5(a)(I)(iv) and its actual or estimated date of publication in the Federal Register, must accompany each request for approval of a collection of information. The Supporting Statement must be prepared in the format described below, and must contain the information specified in Section A below. If an item is not applicable, provide a brief explanation. When Item 17 of the OMB Form 83-I is checked "Yes," Section C of the Supporting Statement must be completed. OMB reserves the right to require the submission of additional information with respect to any request for approval.

Specific Instructions

A. Background

In Decision Memorandum #CAG-00065R, issued on February 26, 2010, the Centers for Medicare and Medicaid Services (CMS) determined that the evidence is sufficient to conclude that for Medicare beneficiaries receiving NaF-18 PET scan to identify bone metastasis in cancer is reasonable and necessary only when the provider is participating in and patients are enrolled in a clinical study designed to information at the time of the scan to assist in initial antitumor treatment planning or to guide subsequent treatment strategy by the identification, location and quantification of bone metastases in beneficiaries in whom bone metastases are strongly suspected based on clinical symptoms or the results of other diagnostic studies. Qualifying clinical studies must ensure that specific hypotheses are addressed; appropriate data elements are collected; hospitals and providers are qualified to provide the PET scan and interpret the results; participating hospitals and providers accurately report data on all Medicare enrolled patients; and all patient confidentiality, privacy, and other Federal laws must be followed. Consistent with section 1142 of the Social Security Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that the CMS determines meet specified standards and address the specified research questions.

B. Justification

1. Need and Legal Basis

   To qualify for payment, providers must prescribe certain NaF-18 PET scans for beneficiaries with a set of clinical criteria specific to each solid tumor. The statuary authority for this policy is section 1862 (a)(1)(E) of the Social Security Act. The need to prospectively collect

information at the time of the scan is to assist the provider in decision making for patient management.

2. Information Users

To qualify for payment, providers must prescribe certain NaF-18 PET scans for beneficiaries with a set of clinical criteria specific to each solid tumor. Data elements will be transmitted to CMS for evaluation of the short and long-term benefits of NaF-18 PET to beneficiaries and for use in future clinical decision making.

3. Use of Information Technology

One-hundred percent of the collection of this information is through electronic means. The usual CMS forms and means of submission for claims by providers for payment will be utilized. In addition, to qualify for payment, providers who prescribe certain NaF-18 PET scans must only do so for beneficiaries with a set of clinical criteria specific to each solid tumor. The entity responsible for the maintaining data continue to maintain an electronic means of data collection for this information needed to justify payment. The collection of data requires a signature from the respondent.

4. Duplication of Efforts

This collection of information does not impact small businesses or other small entities.

5. Small Businesses

If the collection of information impacts small businesses or other small entities (Item 5 of OMB Form 83-I), describe any methods used to minimize burden.

6. Less Frequent Collection

The collection of this data occurs each time a beneficiary undergoes certain NaF-18 PET scans. The physician prescribing the technology will need to submit this information each time the patient undergoes these NaF-18 PET scans. If the information is not collected, CMS cannot meet its responsibility to encourage responsible and appropriate use of NaF-18 PET.

7. Special Circumstances

The respondent (i.e., the provider) is required to report the information to the agency for payment. The provider may perform more than one procedure per quarter and therefore would submit information more often than quarterly.

8. Federal Register/Outside Consultation

Attached is a copy of the 60-day Federal Register notice that published on _____.

The data collection forms and procedures have been developed with stakeholders including specialty societies, industry, clinical researchers, independent PET scan facilities, health plans and hospital associations. The data collection includes baseline beneficiary characteristics; indications for the NaF-18 PET scan; NaF-18 PET scan type and characteristics; NaF-18 PET results; results of all other imaging studies; facility and provider characteristics; solid tumor type; long-term patient outcomes; disease management changes; and anti-cancer treatment received. The clinical data collection ensures that specific hypotheses are identified prospectively; hospitals and providers are qualified to provide the NaF-18 PET and interpret the results; the study adheres to the standards of scientific integrity and relevance to the Medicare beneficiary population; and all patient confidentiality, privacy and other Federal laws are followed.

9. Payments/Gifts to Respondents

No payment or gift will be provided to respondents, other than remuneration for performing the procedure to implant the device.

10. Confidentiality

CMS shall be assured that all applicable patient confidentiality, privacy, and other Federal laws must are complied with, including the Standards for Privacy of Individually Identifiable Health Information (Privacy Rule).

11. Sensitive Questions

No questions of a sensitive nature are included in this data collection.

12. Burden Estimates (Hours & Wages)

A re-evaluation of the burden estimates found them to be unchanged. The burden associated with this requirement is the time and effort necessary for the provider to complete a brief electronic data collection form. We estimate that on average it will take each provider five minutes to complete and transmit a given form. We estimate that approximately 25,000 Medicare beneficiaries will undergo FDG PET for cancer therapeutic or diagnostic indications per year. Therefore, the total annual burden associated with this requirement is 2,084 hours.

13. Capital Costs

There are no capital costs associated with this collection. The software used to complete and transmit the form will be provided free of charge, by downloading the software by the entity collecting the data.

14. Cost to Federal Government

    No annualized cost to the Federal government will be incurred.

15. Changes to Burden

    The burden estimates are unchanged.

16. Publication/Tabulation Dates

    There are no publication or tabulation dates.

17. Expiration Date

    CMS would like an exemption from displaying the expiration date as these forms are used on a continuing basis.

18. Certification Statement

    There are no exemptions to the certification statement.