Supporting Statement – Part A

0968-0968

Supporting Statement For Paperwork Reduction Act Submissions

Specific Instructions

A. Background

In the Decision Memo #CAG-00181N issued on January 27, 2005, CMS determined that the evidence is sufficient to conclude that for Medicare beneficiaries receiving FDG positron emission tomography (PET) for brain, cervical, ovarian, pancreatic, small cell lung, and testicular cancers is reasonable and necessary only when the provider is participating in and patients are enrolled in a systematic data collection project. CMS will consider prospective data collection systems to be qualified if they provide assurance that specific hypotheses are addressed and they collect appropriate data elements. The data collection should include baseline patient characteristics; indications for the PET scan; PET scan type and characteristics; FDG PET results; results of all other imaging studies; facility and provider characteristics; cancer type, grade, and stage; long-term patient outcomes; disease management changes; and anti-cancer treatment received.

B. Justification

1 . Need and Legal Basis

To qualify for payment, providers must prescribe FDG PET for beneficiaries with a set of clinical criteria specific to each cancer type and stage. The statuary authority for this policy is section 1862 (a) (1)(A) 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 FDG PET for beneficiaries with a set of clinical criteria specific to each cancer type and stage. Data elements will be transmitted to CMS for evaluation of the short and long-term benefits of FDG 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 FDG PET must only do so for beneficiaries with a set of clinical criteria specific to each cancer type and stage. Therefore, CMS is requiring stakeholders including specialty societies, industry, health plans and hospital associations to create systematic

clinical databases or registries to be reimbursed for FDG PET for beneficiaries with a set of clinical criteria specific to each cancer type and stage. The entity responsible for the registry will be required to establish an electronic means of data collection for this additional information needed to justify payment. The collection of data does not require a signature from the respondent.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

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

6. Less Frequent Collection

The collection of this data occurs each time a beneficiary undergoes an FDG PET. The physician prescribing the technology will need to submit this information each time the patient undergoes an FDG PET. If the information is not collected, CMS cannot meet its responsibility to encourage responsible and appropriate use of FDG 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 a quarter and therefore would submit information more often than quarterly.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on September 5, 2008.

The data collection forms and procedures will be developed in consultation with stakeholders including specialty societies, industry, clinical researchers, independent scanning facilities, health plans and hospital associations. The data collection should include baseline beneficiary characteristics; indications for the PET scan; PET scan type and characteristics; FDG PET results; results of all other imaging studies; facility and provider characteristics; cancer type, grade, and stage; long-term patient outcomes; disease management changes; and anti-cancer treatment received. The clinical data collection must ensure that specific hypotheses are identified prospectively; hospitals and providers are qualified to provide the FDG PET and interpret the results; and participating hospitals and providers collect prospective data at the time of payment on all enrolled patients undergoing FDG PET for cancer therapeutic or diagnostic indications.

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

The data collected will be kept confidential to the extent provided by law.

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 accurate without changes. 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 2,000 providers will be completing and transmitting forms. We estimate that on average it will take each provider five minutes to complete and transmit a given form. We estimate that approximately 50,000 Medicare beneficiaries will undergo FDG PET for cancer therapeutic or diagnostic indications per year. Therefore, the total annual burden associated with this requirement is 4,167 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 from the national registry.

14. Cost to Federal Government

No annualized cost to the Federal government will be incurred.

15. Changes to Burden

There are no changes to the burden.

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. To include an expiration date would result in having to discard a potentially large number of forms.

18. Certification Statement

There are no exemptions to the certification statement.