Supporting Statement – Part A

Supporting Statement for Paperwork Reduction Act Submissions

A. Background

CMS provides coverage for implantable cardioverter-defibrillators (ICDs) for secondary prevention of sudden cardiac death based on extensive evidence showing that use of ICDs among patients with a certain set of physiologic conditions are effective. Accordingly, CMS considers coverage for ICDs reasonable and necessary under Section 1862 (a) (1) (A) of the Social Security Act. However, evidence for use of ICDs for primary prevention of sudden cardiac death is less compelling for certain patients.

To encourage responsible and appropriate use of ICDs, CMS issued a *Decision Memo for Implantable Defibrillators* on January 27, 2005, indicating that ICDs will be covered for primary prevention of sudden cardiac death if the beneficiary is enrolled in either an FDA-approved category B IDE clinical trial (42 CFR §405.201), a trial under the CMS Clinical Trial Policy (NCD Manual §310.1) or a qualifying prospective data collection system (either a practical clinical trial or prospective systematic data collection, which is sometimes referred to as a registry).

B. Justification

1. Need and Legal Basis

   CMS considers coverage for ICDs reasonable and necessary under Section 1862 (a)(1)(A) of the Social Security Act for primary prevention of sudden cardiac death if the beneficiary is enrolled in either an FDA-approved category B IDE clinical trial (42 CFR §405.201), a trial under the CMS Clinical Trial Policy (NCD Manual §310.1) or a qualifying prospective data collection system (either a practical clinical trial or prospective systematic data collection, which is sometimes referred to as a registry).

2. Information Users

   To qualify for payment, providers must implant cardiac defibrillators only in patients with pre-specified clinical conditions. In addition, CMS is requiring stakeholders including specialty societies, industry, health plans and hospital associations to create systematic clinical data bases or registries to be reimbursed for ICDs implanted for primary prevention. Data elements will be transmitted to CMS at the time of payment for evaluation of safety and benefit of ICDs for its beneficiaries and inform future clinical decision making. The statuary authority for this policy is Section 1862 (a) (1) (A) of the Act.

3. Use of Information Technology

   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 must implant cardiac defibrillators only in patients with pre-specified clinical conditions. Therefore, CMS is requiring stakeholders including specialty societies, industry, health plans and hospital associations to create systematic clinical data bases or registries to be reimbursed for ICDs implanted for primary prevention. The entity responsible for the registry will be required to establish an electronic means of data collection for additional information needed to justify payment.

4. Duplication of Efforts

Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above. If information cannot possibly be obtained from any other source, put here "this information collection does not duplicate any other effort and the information cannot be obtained from any other source"

5. Small Businesses

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

6. Less Frequent Collection

The collection of this data occurs one time only for each patient undergoing the procedure. The physician performing the procedure will need to submit this information one time only for each patient receiving the device. If the information is not collected CMS cannot meet its responsibility to encourage responsible and appropriate use of ICDs.

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

CMS consulted with the National ICD Registry Working Group prior to issuing the *Decision Memo for Implantable Defibrillators* on January 27, 2005, indicating that ICDs will be covered for primary prevention of sudden cardiac death if the beneficiary is enrolled in either an FDA-approved category B IDE clinical trial (42 CFR §405.201), a trial under the CMS Clinical Trial Policy (NCD Manual §310.1) or a qualifying prospective data collection system (either a practical clinical trial or prospective systematic data collection, which is sometimes referred to as a registry). The National ICD Registry Working Group was formed by the Heart Rhythm Society and comprised of representatives of the stakeholders including specialty societies, industry, clinical researchers, health plans and hospital associations. The Group reviewed the following topics to provide comments and recommendations to CMS on a plan to establish a national registry for Medicare beneficiaries receiving an ICD for primary

prevention therapy: purpose of the registry and main question (s) to be answered, clinical characteristics of patients to receive the device, device data elements, defining providers as competent and qualified to implant ICDs, registry management, and registry funding.

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)

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 there will be approximately 1,702 respondents. We further estimate that on average it will take each respondent 60 minutes to complete and transmit a given form. We estimate the total annual burden associated with this requirement is 139,656 hours.

13. Capital Costs

There is no capital costs associated with this collection.

14. Cost to Federal Government

No annualized cost to the Federal government will be incurred.

15. Changes to Burden

There are changes to the burden. The data collection form has changed significantly to delete data elements and fields that were found to be no longer applicable. While some additional data elements were added due to the collection of important information regarding device lead placement, many fields also were greatly improved by better field descriptors and definitions. The majority of the increased time necessary to complete the data form is due to the additional data elements related to device lead placement.

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.