

Supporting Statement –
Part A

**Data Collection for Medicare Beneficiaries Receiving Implantable
Cardioverter-defibrillators for Primary Prevention of Sudden Cardiac
Death (CMS-10151)**

A. Background

This is a request to reinstate this information collection. The original information collection was discontinued in 2016 as a result of ongoing internal policy deliberations. At the conclusion of those deliberations a determination was made to reinstate this information collection.

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

Data elements will be used for evaluation of safety and benefit of ICDs for beneficiaries and inform future clinical decision making.

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

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

5. Small Businesses

We do not anticipate that small businesses would be affected by this collection. This information is submitted by hospitals.

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

The 60-day Federal Register notice published on February 17, 2017 (82 FR 11040). There were no public comments received.

The 30-day Federal Register notice published on April 28, 2017 (82 FR 19734).

Prior to issuing this long standing policy, CMS consulted with the National ICD Registry Working Group 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 be 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 1,600 respondents. We further estimate that on average it will take each respondent 15 minutes to complete and transmit a given form and we estimate a total of 80,000 forms will be transmitted per year. We estimate the total annual burden associated with this requirement is 20,000 hours. According to the Bureau of Labor Statistics www.bls.gov, the median hourly wage for a nurse (the type of professional that typically completes the forms) in 2016 was \$69.40 (including 100% fringe benefits). The annual cost burden is thus calculated at \$1,388,000.

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 changes to burden are due to calculations based on averages of the actual number of primary prevention ICD procedures performed in 2012 and 2013 and

changes to the estimated time it takes to complete and transmit each form. The original numbers were estimates that were not based on experience as these were new processes at the time. The burden hours were 139,656 in the previously approved ICR which was discontinued. The current burden hours are 20,000.

16. Publication/Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

The OMB control number and corresponding expiration date will be displayed on the data collection form.

18. Certification Statement

There are no exemptions to the certification statement.