DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services


Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by May 30, 2017.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 OR, Email: OIRA_submission@omb.eop.gov.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:


2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. (The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)[A]) requires federal agencies to publish a 30-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. Comments submitted in response to the 60-day FR Notice have been addressed in Appendix A of the ICR. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Reconciliation of State Invoice and Prior Quarter Adjustment Statement; Use: Form CMS–304 (Reconciliation of State Invoice) is used by manufacturers to respond to the state’s rebate invoice for current quarter utilization. Form CMS–304a (Prior Quarter Adjustment Statement) is required only in those instances where a change to the original rebate data submittal is necessary. Form Number: CMS–304 and –304a (OMB control number: 0938–0676); Frequency: Quarterly; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 56; Total Annual Responses: 224; Total Annual Hours: 12,101. (For policy questions regarding this collection contact Andrea Wellington at 410–786–3490.)

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To encourage responsible and appropriate use of ICDs, we 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). Form Number: CMS–10151 (OMB control number: 0938–0967); Frequency: Occasionally; Affected Public: Business or other for-profits, Not-for-profit institutions; Number of Respondents: 1,600; Total Annual Responses: 80,000; Total Annual Hours: 20,000. (For policy questions regarding this collection contact JoAnna Baldwin at 410–786–7205.)

2. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Data Collection for Medicare Facilities Performing Carotid Artery Stenting with Embolic Protection in Patients at High Risk for Carotid Endarterectomy; Use: We provide coverage for carotid artery stenting (CAS) with embolic protection for patients at high risk for carotid endarterectomy and who also have symptomatic carotid artery stenosis between 50 percent and 70 percent or have asymptomatic carotid artery stenosis 80 percent in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), a trial under the CMS Clinical Trial Policy (NCD Manual § 310.1, or in accordance with the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7). Accordingly, we consider coverage for CAS reasonable and necessary (section 1862(a)(1)(a) of the Social Security Act). However, evidence for use of CAS with embolic protection for patients with high risk for carotid endarterectomy and who also have symptomatic carotid artery stenosis ≥70 percent who are not enrolled in a study or trial is less compelling. To encourage responsible and appropriate use of CAS with embolic protection, we issued a Decision Memo for Carotid Artery Stenting on March 17, 2005, indicating that CAS with embolic protection for symptomatic carotid artery stenosis ≥70 percent will be covered only if performed in facilities that have been determined to be competent in