



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-304/304a, CMS-368/CMS-R-144, CMS-R-308, CMS-10151, CMS-10199, CMS-R-13, and CMS-10279]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by **INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER**.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

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:

1. Access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. E-mail 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: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

CMS-304/304a Reconciliation of State Invoice and Prior Quarter Adjustment Statement

CMS-368/CMS-R-144 Medicaid Drug Rebate Program Forms

CMS-R-308 State Children's Health Insurance Program and Supporting Regulations

CMS-10151 Data Collection for Medicare Beneficiaries Receiving Implantable
Cardioverter-Defibrillators for Primary Prevention of Sudden Cardiac Death

CMS-10199 Data Collection for Medicare Facilities Performing Carotid Artery Stenting
with Embolic Protection in Patients at High Risk for Carotid Endarterectomy

CMS-R-13 Conditions of Coverage for Organ Procurement Organizations and Supporting
Regulations at Children's Health Insurance Program and Supporting
Regulations

CMS-10279 Ambulatory Surgical Center Conditions for Coverage

Under the 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 requires federal agencies to publish a 60-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. To comply with this requirement, CMS is publishing this notice.

Information Collection

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: Business or other for-profits; Number of Respondents: 1,037; Total Annual Responses: 4,148; Total Annual Hours: 187,880. (For policy questions regarding this collection contact Andrea Wellington at 410-786-3490.)

2. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicaid Drug Rebate Program Forms; Use: We develop the rebate amount per drug unit from information supplied by the drug manufacturers and distributes these data to the states. States then must report quarterly to the drug manufacturers and report to us the total number of units of each dosage form/strength of their covered outpatient drugs reimbursed during a quarter and the rebate amount to be refunded. This report is due within 60 days of the end of each calendar quarter. The information in the report is based on claims paid by the state Medicaid agency during a calendar quarter. Form CMS-R-144 (Quarterly Report Data) is required from states quarterly to report utilization for any drugs paid for during that quarter. Form CMS-368 (Administrative Data) is required only in those instances where a change to the original data submittal is necessary. Form Number: CMS-368 and -R-144 (OMB control number: 0938-0582); 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.)

3. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: State Children's Health Insurance Program and Supporting Regulations; Use: States must submit title XXI plans and amendments for approval by the Secretary. We use the plan and its subsequent amendments to determine if the state has met the requirements of title XXI. Information provided in the state plan, state plan amendments, and from the other information we are collecting will be

used by advocacy groups, beneficiaries, applicants, other governmental agencies, providers groups, research organizations, health care corporations, health care consultants. States will use the information collected to assess state plan performance, health outcomes and an evaluation of the amount of substitution of private coverage that occurs as a result of the subsidies and the effect of the subsidies on access to coverage. Form Number: CMS-R-308 (OMB control number: 0938-0841); Frequency: Yearly, Once, and Occasionally; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 56; Total Annual Responses: 28,294,596; Total Annual Hours: 1,473,885. (For policy questions regarding this collection contact Amy Lutzky at 410-786-0721).

4. Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title of Information Collection: Data Collection for Medicare Beneficiaries Receiving Implantable Cardioverter-Defibrillators for Primary Prevention of Sudden Cardiac Death; Use: We provide 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, we consider 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, 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.)

5. Type of Information Collection Request: Extension 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 \geq 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 \geq 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 \geq 70 percent will be covered only if performed in facilities that have been determined to be competent in performing the evaluation, procedure and follow-up necessary to ensure optimal patient outcomes. In accordance with this criteria, we consider coverage for CAS reasonable and necessary (section 1862 (A)(1)(a) of the Social Security Act). Form Number: CMS-10199 (OMB control number: 0938-1011); Frequency: Yearly; Affected Public: Business or other for-profit and Not-for-profit institutions; Number of Respondents: 1,000; Total Annual Responses:

1,000; Total Annual Hours: 500. (For policy questions regarding this collection contact Sarah Fulton at 410-786-2749.)

6. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Conditions of Coverage for Organ Procurement Organizations and Supporting Regulations; Use: Section 1138(b) of the Social Security Act, as added by section 9318 of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99-509), sets forth the statutory qualifications and requirements that organ procurement organizations (OPOs) must meet in order for the costs of their services in procuring organs for transplant centers to be reimbursable under the Medicare and Medicaid programs. An OPO must be certified and designated by the Secretary as an OPO and must meet performance-related standards prescribed by the Secretary. The corresponding regulations are found at 42 CFR Part 486 (Conditions for Coverage of Specialized Services Furnished by Suppliers) under subpart G (Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations).

Since each OPO has a monopoly on organ procurement within its designated service area (DSA), we must hold OPOs to high standards. Collection of this information is necessary for us to assess the effectiveness of each OPO and determine whether it should continue to be certified as an OPO and designated for a particular donation service area by the Secretary or replaced by an OPO that can more effectively procure organs within that DSA. Form Number: CMS-R-13 (OMB control number: 0938-0688); Frequency: Occasionally; Affected Public: Not-for-profit institutions; Number of Respondents: 58; Total Annual Responses: 58; Total Annual Hours: 13,546. (For policy questions regarding this collection contact Diane Corning at 410-786-8486.)

7. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Ambulatory Surgical Center Conditions for Coverage; Use: The Ambulatory Surgical

Center (ASC) Conditions for Coverage (CfCs) focus on a patient-centered, outcome-oriented, and transparent processes that promote quality patient care. The CfCs are designed to ensure that each facility has properly trained staff to provide the appropriate type and level of care for that facility and provide a safe physical environment for patients. The CfCs are used by Federal or state surveyors as a basis for determining whether an ASC qualifies for approval or re-approval under Medicare. We, along with the healthcare industry, believe that the availability to the facility of the type of records and general content of records, which this regulation specifies, is standard medical practice and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability. Form Number: CMS-10279 (OMB control number: 0938-1071); Frequency: Annual; Affected Public: Business or other for-profit and Not-for-profit institutions; Number of Respondents: 5,500; Total Annual Responses: 5,500; Total Annual Hours: 209,000. (For policy questions regarding this collection contact Jacqueline Leach at 410-786-4282.)

Dated: February 14, 2017

William N. Parham, III

Director, Paperwork Reduction Staff

Office of Strategic Operations and Regulatory Affairs

Billing Code: 4120-01-U-P

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