DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10199, CMS–10484, CMS–R–38, CMS–10237, CMS–10198, CMS–R–267, CMS–10137, CMS–43, CMS–1763, CMS–1728–94, CMS–10174, CMS–10305 and CMS–10488]

Agency Information Collection Activities: Proposed Collection; 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 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 any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by August 27, 2013:

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). 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. 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: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: 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–10199 Data Collection for Medicare Facilities Performing Carotid Artery Stenting with Embolic Protection in Patients at High Risk for Carotid Endarterectomy

CMS–10484 End Stage Renal Disease (ESRD) Application Access Request Form

CMS–R–38 Conditions of Certification for Rural Health Clinics

CMS–10266 Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers to Perform Organ Transplants

CMS–10237 Part C—Medicare Advantage and 1876 Cost Plan Expansion Application

CMS–10198 Collection Requirements Pertaining to the Creditable Coverage Disclosure to CMS On-Line Form and Instructions

CMS–R–267 Medicare Advantage Program Requirements

CMS–10137 Solicitation for Applications for Medicare Prescription Drug Plan 2015 Contracts

CMS–43 Application for Hospital Insurance Benefits for Individuals with End Stage Renal Disease

CMS–1763 Request for Termination of Premium Hospital and/or Supplementary Medical Insurance

CMS–1728–94 Home Health Agency Cost Report

CMS–10174 Collection of Prescription Drug Event Data from Contracted Part D Providers for Payment

CMS–10305 Part C Medicare Advantage Reporting Requirements and Supporting Regulations

CMS–10488 Enrollee Satisfaction Survey Data Collection

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 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 Collections

1. *Type of Information Collection Request:* Reinstatement without change of a previously 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 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 (OCN: 0938–1011); *Frequency:* Yearly; *Affected Public:* Business or other for-profit, 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 Lori Ashby at 410–786–6322.)

2. *Type of Information Collection Request:* New Collection (Request for a new OMB control number); *Title of Information Collection:* End Stage Renal Disease (ESRD) Application Access Request Form; *Use:* We are developing a new suite of systems to support the End Stage Renal Disease (ESRD) program. Due to the sensitivity of the data being collected and reported, we must ensure that only authorized personnel have access to data. Personnel are given access to the ESRD systems through the creation of user IDs and passwords within the QualityNet Identity Management System (QIMS); however, once within the system, the system determines the rights and privileges the personnel has over the data within the system. Such access rights include: Viewing and reporting, updating adding and deleting.

The sole purpose of the ESRD Application Access Request Form is to identify the individual's data access rights once within the ESRD system. This data collection is currently being accomplished under ''Part B'' of the QualityNet Identity Management System Account Form. Once the ESRD Application Access Form is approved, the QualityNet Identity Management System (QIMS) Account Form will be revised to remove Part B from the QIMS data collection. The ESRD Application Access Request Form will be a new form and will be assigned its own OMB Control number. The ESRD system accounts created using the current QIMS Account Form—Part B will not need to submit an ESRD Application Access Form for the creation of their account since that information was collected under Part B.

The QIMS Account Registration and the ESRD Application Access Request forms are required for identity and security management of individuals accessing the Consolidated Renal Operations in a Web Enabled Network (CROWNWeb) system and the End Stage Renal Disease Quality Incentive Program (ESRD QIP) system. The CROWNWeb system is the system that is mandated for the Medicare and Medicaid Programs Conditions of Coverage for End-Stage Renal Disease Facilities, Final Rule published April 15, 2008. *Form Number:* CMS–10484 (OCN: 0938–NEW); *Frequency:* Annually; *Affected Public:* Business and other for-profits; and not-for-profits; *Number of Respondents:* 27,000; *Total Annual Responses:* 27,000; *Total Annual Hours:* 6,750. (For policy questions regarding this collection contact Victoria Schlining at 410–786–6878.)

3. *Type of Information Collection Request:* Reinstatement with change of a currently approved collection; *Title of Information Collection:* Conditions of Certification for Rural Health Clinics; *Use:* The Rural Health Clinic (RHC) conditions of certification are based on criteria prescribed in law and are designed to ensure that each facility has a properly trained staff to provide appropriate care and to assure a safe physical environment for patients. We use these conditions of participation to certify RHCs wishing to participate in the Medicare program. These requirements are similar in intent to standards developed by industry organizations such as the Joint Commission on Accreditation of Hospitals, and the National League of Nursing and the American Public Association and merely reflect accepted standards of management and care to which rural health clinics must adhere. *Form Number:* CMS–R–38 (OCN: 0938–0334); *Frequency:* Recordkeeping and Reporting—Annually; *Affected Public:* Business or other for-profits; *Number of Respondents:* 9,716; *Total Annual Responses:* 9,716; *Total Annual Hours:* 33,304. (For policy questions regarding this collection contact Mary Collins at 410–786–3189.)

4. *Type of Information Collection Request:* Reinstatement with change of a currently approved collection; *Title of Information Collection:* Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers to Perform Organ Transplants; *Use:* The Conditions of Participation and accompanying requirements specified in the regulations are used by our surveyors as a basis for determining whether a transplant center 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 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–10266 (OCN: 0938–1069); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 226; *Total Annual Responses:* 528; *Total Annual Hours:* 2,523. (For policy questions regarding this collection contact Diane Corning at 410–786–8486.)

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Part C—Medicare Advantage and 1876 Cost Plan Expansion Application; *Use:* Organizations wishing to provide healthcare services under Medicare Advantage (MA) and/or MA organizations that offer integrated prescription drug and health care products must complete an application, file a bid, and receive final approval from us. Existing MA plans may request to expand their contracted service area by completing the Service Area Expansion application. Any current 1876 Cost Plan Contractor that wants to expand its Medicare cost-based contract with CMS can complete the application. Information is collected to ensure applicant compliance with our requirements and to gather data used to support its determination of contract awards. *Form Number:* CMS–10237 (OCN 0938–0935); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profits institutions; *Number of Respondents:* 566; *Total Annual Responses:* 566; *Total Annual Hours:* 22,955. (For policy questions regarding this collection contact Melissa Staud at 410–786–3669.)

6. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Creditable Coverage Disclosure to CMS On-Line Form and Instructions; *Use:* Most entities that currently provide prescription drug benefits to any Medicare Part D eligible individual must disclose whether their prescription drug benefit is creditable (expected to pay at least as much, on average, as the standard prescription drug plan under Medicare). The disclosure must be provided annually and upon any change that affects whether the coverage is creditable prescription drug coverage. *Form Number:* CMS–10198 (OCN: 0938–1013). *Frequency:* Yearly and semi-annually; *Affected Public:* Business or other for-profits and not-for-profit institutions, State, Local, or Tribal Governments. *Number of Respondents:* 85,610; *Total Annual Responses:* 87,265; *Total Annual Hours:* 7,272. (For policy questions regarding this

collection contact Roslyn Thomas at 410–786–9621.)

7. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Medicare Advantage Program Requirements; *Use:* Medicare Advantage (MA) organizations and potential MA organizations (applicants) use the information to comply with the application requirements and the MA contract requirements. We will use this information to: Approve contract applications, monitor compliance with contract requirements, make proper payment to MA organizations, determine compliance with the new prescription drug benefit requirements, and to ensure that correct information is disclosed to Medicare beneficiaries (both potential enrollees and enrollees). *Form Number:* CMS–R–267 (OCN: 0938–0753). *Frequency:* Yearly. *Affected Public:* Individuals or households and Business or other for-profits; *Number of Respondents:* 18,043,776; *Total Annual Responses:* 21,935,728; *Total Annual Hours:* 8,529,541. (For policy questions regarding this collection contact Dana Burley at 410–786–4547.)

8. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Solicitation for Applications for Medicare Prescription Drug Plan 2015 Contracts; *Use:* The information will be collected under the solicitation of proposals from prescription drug plans, Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage, Cost Plans, PACE, and EGWP applicants. We will use the information collected to ensure that applicants meet our requirements and to support the determination of contract awards. *Form Number:* CMS–10137 (OCN: 0938–0936); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profits institutions; *Number of Respondents:* 254; *Total Annual Responses:* 254; *Total Annual Hours:* 2,319. (For policy questions regarding this collection contact Linda Anders at 410–786–0459.)

9. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Application for Hospital Insurance Benefits for Individuals with End Stage Renal Disease; *Use:* The CMS–43 application is used (in conjunction with CMS–2728) to establish entitlement to, and enrollment in, Medicare Part A (and Part B) for individuals with end stage renal disease. The application is completed by a Social Security Administration (SSA) claims representative or field representative using information provided by the individual during an interview. The CMS–43 application follows the questions and requirements used by SSA to determine Title II eligibility. This is done not only for consistency purposes, but because certain Title II and Title XVIII insured status and relationship requirements must be met in order to qualify for Medicare under the end stage renal disease provisions. *Form Number:* CMS–43 (OCN: 0938–0800); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 60,000; *Total Annual Responses:* 60,000; *Total Annual Hours:* 24,960. (For policy questions regarding this collection contact Lindsay Smith at 410–786–6843.)

10. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Request for Termination of Premium Hospital and Supplementary Medical Insurance; *Use:* The CMS–1763 provides us and the Social Security Administration (SSA) with the enrollee's request for termination of Part B, Part A or both Part B and A premium coverage. The form is completed by an SSA claims or field representative using information provided by the Medicare enrollee during an interview. The purpose of the form is to provide to the enrollee with a standardized format to request termination of Part B, Part A premium coverage or both, explain why the enrollee wishes to terminate such coverage, and to acknowledge that the ramifications of the decision are understood. *Form Number:* CMS–1763 (OCN: 0938–0025); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 14,000; *Total Annual Responses:* 14,000; *Total Annual Hours:* 5,833. (For policy questions regarding this collection contact Lindsay Smith at 410–786–6843.)

11. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Home Health Agency Cost Report; *Use:* In accordance with sections 1815(a), 1833(e) and 1861(v)(1)(A) of the Social Security Act, providers of service in the Medicare program are required to submit annual information to achieve reimbursement for health care services rendered to Medicare beneficiaries. In addition, 42 CFR 413.20(b) requires that cost reports are required from providers on an annual basis. Such cost reports are required to be filed with the provider's Medicare contractor. The Medicare contractor uses the cost report not only to make settlement with the provider for the fiscal period covered by the cost report, but also in deciding whether to audit the records of the provider. Section 413.24(a) requires providers receiving payment on the basis of reimbursable cost provide adequate cost data based on their financial and statistical records that must be capable of verification by qualified auditors. Besides determining program reimbursement, the data submitted on the cost reports supports the management of federal programs. The data is extracted from the cost report and used for making projections of Medicare Trust Fund requirements and for analysis to rebase home health agency prospective payment system. The data is also available to Congress, researchers, universities, and other interested parties. While the collection of data is a secondary function of the cost report, its primary function is to reimburse providers for services rendered to program beneficiaries. *Form Number:* CMS–1728–94 (OCN: 0938–0022): *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 11,563; *Total Annual Responses:* 11,563; *Total Annual Hours:* 2,613,238. (For policy questions regarding this collection contact Angela Havrilla at 410–786–4516.)

12. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Collection of Prescription Drug Event Data from Contracted Part D Providers for Payment; *Use:* The information users for this information collection request include Pharmacy Benefit Managers, third party administrators and pharmacies and prescription drug plans, Medicare Advantage plans that offer integrated prescription drug and health care coverage, Fallbacks and other plans that offer coverage of outpatient prescription drugs under the Medicare Part D benefit to Medicare beneficiaries. The data is used primarily for payment, but is also used for claim validation as well as for other legislated functions such as quality monitoring, program integrity, and oversight. *Form Number:* CMS–10174 (OCN: 0938–0982); *Frequency:* Monthly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 747; *Total Annual Responses:* 947,881,770; *Total Annual Hours:* 1,896. (For policy questions regarding this collection contact Ivan Iveljic at 410–786–3312.)

13. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Part C Medicare Advantage Reporting Requirements and Supporting Regulations; *Use:* There are a number of information users of Part C reporting, including central and regional office staff that use this information to monitor health plans and to hold them accountable for their performance. Other government agencies such as the Government Accountability Office have inquired about this information. Health plans can use this information to measure and benchmark their performance. CMS intends to make some of these data available for public reporting as ''display measures'' in 2013. *Form Number:* CMS–10305 (OCN: 0938–1115); *Frequency:* Yearly and semi-annually; *Affected Public:* Business or other for-profits; *Number of Respondents:* 588; *Total Annual Responses:* 6,715; *Total Annual Hours:* 200,918. (For policy questions regarding this collection contact Terry Lied at 410–786–8973.)

14. *Type of Information Collection Request:* New Collection (Request for a new OMB control number; *Title of Information Collection:* Enrollee Satisfaction Survey Data Collection; *Use:* Section 1311(c)(4) of the Affordable Care Act (ACA) requires the Department of Health and Human Services (HHS) to develop an enrollee satisfaction survey system that assesses consumer experience with qualified health plans (QHPs) offered through an Exchange. It also requires public display of enrollee satisfaction information by the Exchange to allow individuals to easily compare enrollee satisfaction levels between comparable plans. HHS intends to establish an enrollee satisfaction survey system that assesses consumer experience with the Marketplaces and the qualified health plans (QHPs) offered through the Marketplaces. The surveys will include topics to assess consumer experience with the Marketplace such as enrollment and customer service, as well as experience with the health care system such as communication skills of providers and ease of access to health care services. We are considering using the Consumer Assessment of Health Providers and Systems (CAHPS®) principles (*http://www.cahps.ahrq.gov/about.htm*) for developing the surveys. We are also considering an application and approval process for enrollee satisfaction survey vendors who want to participate in collecting ESS data. The application form for survey vendors includes information regarding organization name and contact(s) as well as minimum business requirements such as relevant survey experience, organizational survey capacity, and quality control procedures.

The Marketplace Survey will provide (1) actionable information that the Marketplaces can use to improve performance, (2) information that we and state regulatory organizations can use for oversight, and (3) a longitudinal database for future Marketplace research. The CAHPS® family of instruments does not have a survey that assesses entities similar to Marketplaces, so the Marketplace survey items were generated by the project team. The QHP survey will (1) help consumers choose among competing health plans, (2) provide actionable information that the QHPs can use to improve performance, (3) provide information that regulatory and accreditation organizations can use to regulate and accredit plans, and (4) provide a longitudinal database for consumer research. CMS plans to base the QHP survey on the CAHPS® Health Plan Survey.

We are planning for two rounds of developmental testing for the Marketplace and QHP surveys. The 2014 survey field tests will help determine psychometric properties and provide an initial measure of performance for Marketplaces and QHPs to use for quality improvement. Based on field test results, there will be further refinement of the questionnaires and sampling designs to conduct the 2015 beta test of each survey. We plan to request clearance for two additional rounds of national implementation with public reporting of scores for each survey in the future. A summary of findings from the testing rounds will be included when requesting clearance for the additional two rounds of national implementation with public reporting, which will take place in 2016 and 2017. *Form Number:* CMS–10488 (OCN: 0938–NEW); *Frequency:* Annually; *Affected Public:* Individuals and Households, Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 251,671; *Total Annual Responses:* 251,671; *Total Annual Hours:* 86,014. (For policy questions regarding this collection contact Kathleen Jack at 410–786–7214.)

Dated: June 25, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–15558 Filed 6–27–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

New Policies and Procedural Requirements for Electronic Submission of State Plans, and Program and Financial Reporting Forms, for Mandatory Grant Programs

AGENCY: Office of Administration (OA), Administration for Children and Families (ACF), Department of Health and Humans Services (HHS).

ACTION: Notice for public comment of new policies and procedural requirements for the electronic submission of State plans, and program and financial reporting forms, for mandatory grant programs.

SUMMARY: The Administration for Children and Families (ACF), an Operating Division of the Department of Health and Human Services (HHS), announces the opportunity for public comment on our plan to implement required electronic submission of State plans, which includes applications as applicable; and programmatic and financial reporting forms, for mandatory grant programs. In accordance with the e-Government initiatives mandated by the Federal Financial Assistance Management Improvement Act of 1999, ACF officially acknowledges that electronically generated and/or stored documents are recognized equivalents of an official paper grant file. Recognizing the equivalency of such documents eliminates duplicative effort and administrative burden for Federal grant applicants, recipients, and the awarding agency, by facilitating the submission and storage of official grant files. ACF has previously afforded recipients of mandatory State grant programs the option of submitting State plans, and programmatic and financial reporting forms, in both electronic and paper formats. This notice announces that recipients of mandatory State grant programs will now be required to submit State plans, and programmatic and financial reporting forms, electronically. The electronic portal used to support this effort is the ACF On-Line Data Collection (OLDC) system, which is available to State applicants and grantees at *https://extranet.acf.hhs.gov/oldcdocs/materials.html*.

DATES: Submit written or electronic comments on the policies and procedures announced in this Notice, on or before August 27, 2013.