



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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Agency Information Collection Activities: Submission for OMB Review; 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 (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 **[INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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

E-mail: 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:

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: 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. 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 previously approved collection; Title of Information Collection: Advance Directives (Medicare and Medicaid) and Supporting Regulations; Use: The advance directives requirement was enacted because Congress wanted individuals to know that they have a right to make health care decisions and to refuse treatment even when they are unable to communicate. Steps have been taken at both the Federal and State level, to afford greater opportunity for the individual to participate in decisions made concerning the medical treatment to be received by an adult patient in the event that the patient is unable to communicate to others, a preference about medical treatment. The individual may make his preference known through the use of an advance directive, which is a written instruction prepared in advance, such as a living will or durable power of attorney. This information is documented in a prominent part of the individual’s medical record. Advance directives as described in the Patient Self-Determination Act have increased the individual’s control over

decisions concerning medical treatment. Sections 4206 of the Omnibus Budget Reconciliation Act of 1990 defined an advance directive as a written instruction recognized under State law relating to the provision of health care when an individual is incapacitated (those persons unable to communicate their wishes regarding medical treatment).

All states have enacted legislation defining a patient's right to make decisions regarding medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives. Participating hospitals, skilled nursing facilities, nursing facilities, home health agencies, providers of home health care, hospices, religious nonmedical health care institutions, and prepaid or eligible organizations (including Health Care Prepayment Plans (HCPPs) and Medicare Advantage Organizations (MAOs) such as Coordinated Care Plans, Demonstration Projects, Chronic Care Demonstration Projects, Program of All Inclusive Care for the Elderly, Private Fee for Service, and Medical Savings Accounts must provide written information, at explicit time frames, to all adult individuals about: a) the right to accept or refuse medical or surgical treatments; b) the right to formulate an advance directive; c) a description of applicable State law (provided by the State); and d) the provider's or organization's policies and procedures for implementing an advance directive. Form Number: CMS-R-10 (OMB control number: 0938-0610); Frequency: Yearly; Affected Public: Business or other for-profits; Number of Respondents: 39,479; Total Annual Responses: 39,479; Total Annual Hours: 2,836,441. (For policy questions regarding this collection contact Jeannine Cramer at 410-786-5664.)

2. Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Conditions for Payment of Power Mobility Devices, including Power Wheelchairs and Power-Operated Vehicles; Use: We are renewing our request for approval for the collection requirements associated with the final rule, CMS-3017-F (71 FR 17021), which published on April 5, 2006, and required a face-to-face examination of the beneficiary by the physician or treating practitioner, a written prescription, and receipt of pertinent parts of the medical record by the supplier within 45 days after the face-to-face examination that the durable medical equipment (DME) suppliers maintain in their records and make available to CMS and its agents upon request. Form Number: CMS-10116 (OMB control number: 0938-0971); Frequency: Yearly; Affected Public: Business or other for-profits; Number of Respondents: 46,000; Number of Responses: 72,500; Total Annual Hours: 14,434. (For policy questions regarding this collection contact Stuart Caplan at 410-786-8564)

3. Type of Information Collection Request: Revision of a currently approved collection;

Title of Information Collection: Clinical Laboratory Improvement Amendments (CLIA) Regulations; Use: The information is necessary to determine an entity's compliance with the Congressionally-mandated program with respect to the regulation of laboratory testing (CLIA). In addition, laboratories participating in the Medicare program must comply with CLIA requirements as required by section 6141 of OBRA 89. Medicaid, under the authority of section 1902(a)(9)(C) of the Social Security Act, pays for services furnished only by laboratories that meet Medicare (CLIA) requirements. Form Number: CMS-R-26 (OMB Control Number: 0938-0612); Frequency: Monthly, occasionally; Affected Public: Business or other for-profits and Not-for-profit institutions, State, Local or Tribal Governments, and the Federal government;

Number of Respondents: 70,861; Total Annual Responses: 1,979,300; Total Annual Hours: 14,975,785. (For policy questions regarding this collection contact Raelene Perfetto at 410-786-6876).

4. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicare/Medicaid Demonstration/Model Application; Use: The application is used for solicitation of proposals that are either congressionally mandated or Administration high priority demonstration initiatives which would be used to strengthen and modernize the Medicare and/or Medicaid programs. The standardized proposal format is not controversial and will reduce burden on applicants and reviewers. Responses are strictly voluntary. The standard format will enable CMS to select proposals that meet CMS objectives and show the best potential for success. Form Number: CMS-10069 (OMB control number: 0938-0880); Frequency: Once; Affected Public: Business or other for-profits and Not-for-profit institutions; Number of Respondents: 75; Total Annual Responses: 75; Total Annual Hours: 6,000. (For policy questions regarding this collection contact John Amoh at 410-786-4910).

5. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Waiver Application for Providers and Suppliers Subject to an Enrollment Moratorium; Use: This demonstration, in conjunction with an expansion of the existing provider enrollment moratoria, will allow CMS to mitigate known vulnerabilities within the existing moratoria and will lead to increased investigations of fraud. Section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1(a)(1)(J)) permits the Secretary to ``develop or demonstrate improved methods for the investigation and prosecution of fraud in the

provision of care or services under the health programs established by the Social Security Act." In addition to the development and demonstration of improved methods for investigations, CMS will utilize this demonstration to address beneficiary access to care issues. CMS received one comment during the 60-day comment period (81 FR 75408). Form Number: CMS-10629 (OMB control number: 0938-1313); Frequency: Occasionally; Affected Public: Business or other for-profit, Not-for-profit institutions; Number of Respondents: 800; Total Annual Responses: 800; Total Annual Hours: 4,800. (For policy questions regarding this information collection contact Kim Jung at 410-786-9370).

6. Type of Information Collection Request: Extension of a previously 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 (OMB Control Number: 0938-1069); Frequency: Yearly; Affected Public: Business or other for-profits and Not-for-profit institutions; Number of Respondents: 165; Total Annual Responses: 425; Total Annual Hours: 2,593. (For policy questions regarding this collection contact Diane Corning at 410-786-8486.)

7. Type of Information Collection Request: Reinstatement without change of a previously

approved collection; Title of Information Collection: 1915(c) Home and Community Based Services (HCBS) Waiver; Use: We will use the web-based application to review and adjudicate individual waiver actions. The web-based application will also be used by states to submit and revise their waiver requests. Form Number: CMS-8003 (OMB control number 0938-0449); Frequency: Yearly; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 47; Total Annual Responses: 71; Total Annual Hours: 6,005. (For policy questions regarding this collection contact Kathy Poisal at 410-786-5940.)

8. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Request for Enrollment in Supplementary Medical Insurance; Use: Form CMS-4040 is used to establish entitlement to and enrollment in Medicare Part B for beneficiaries who file for Part B only. The collected information is used to determine entitlement for individuals who meet the requirements in section 1836(2) of the Social Security Act as well as the entitlement of the applicant (or their spouses) to an annuity paid by OPM for premium deduction purposes. Form Number: CMS-4040 (OMB control number: 0938-0245); Frequency: Once; Affected Public: Individuals or households; Number of Respondents: 10,000; Total Annual Responses: 10,000; Total Annual Hours: 2,500. (For policy questions regarding this collection contact Carla Patterson at 410-786-8911.)

9. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Retiree Drug Subsidy (RDS) Application and Instructions; Use: Plan sponsors (e.g., employers, unions) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28 percent tax-free subsidy for allowable drug costs. To

qualify, plan sponsors must submit a complete application with a list of retirees for whom it intends to collect the subsidy. Once we review and analyze the information on the application and the retiree list, notification will be sent to the plan sponsor about its eligibility to participate in the RDS program. Form Number: CMS-10156 (OMB control number: 0938-0957); Frequency: Yearly and monthly; Affected Public: Business or other for-profits and Not-for-profit institutions; Number of Respondents: 2,482; Total Annual Responses: 2,482; Total Annual Hours: 158,848. (For policy questions regarding this collection contact Ivan Iveljic at 410-786-3312.)

10. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Retiree Drug Subsidy (RDS) Payment Request and Instructions; Use: Plan sponsors (e.g., employers, unions) who offer prescription drug coverage meeting specified criteria to their qualified covered retirees are eligible to receive a 28 percent tax-free subsidy for allowable drug costs. Plan sponsors must submit required prescription drug cost data and other information in order to receive the subsidy. Plan sponsors may elect to submit RDS payment requests on a monthly, quarterly, interim annual, or annual basis; once selected, the payment frequency may not be changed during the plan year. Form Number: CMS-10170 (OMB control number: 0938-0977); Frequency: Occasionally; Affected Public: Business or other for-profits and Not-for-profit institutions; Number of Respondents: 2,482; Total Annual Responses: 2,482; Total Annual Hours: 374,782. (For policy questions regarding this collection contact Ivan Iveljic at 410-786-3312.)

11. Type of Information Collection Request: Extension of a currently 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 (OMB control number: 0938-1013); Frequency: Yearly and semi-annually; Affected Public: Business or other for-profits and Not-for-profit institutions, and State, Local, or Tribal Governments; Number of Respondents: 85,635; Total Annual Responses: 87,265; Total Annual Hours: 7,272. (For policy questions regarding this collection contact Tammie Wall at 410-786-3317.)

12. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: PACE State Plan Amendment Preprint; Use: If a state elects to offer PACE as an optional Medicaid benefit, it must complete a state plan amendment preprint packet described as “Enclosures 3, 4, 5, 6, and 7.” CMS will review the information provided in order to determine if the state has properly elected to cover PACE services as a state plan option. In the event that the state changes something in the state plan, only the affected page must be updated. Form Number: CMS-10227 (OMB control number: 0938-1027); Frequency: Once and occasionally; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 7; Total Annual Responses: 2; Total Annual Hours: 140. (For policy questions regarding this collection contact Angela Cimino at 410-786-2638.)

13. Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Elimination of Cost-Sharing for Full Benefit Dual-Eligible Individuals Receiving Home and Community-Based Services; Use: This collection eliminates Part D cost-sharing for full benefit dual-eligible beneficiaries who are receiving home and community based services. In this regard, states are required to identify the affected beneficiaries in their monthly Medicare Modernization Act Phase Down reports. Form Number: CMS-10344 (OMB control number: 0938-1127); Frequency: Monthly; Affected Public: Business or other for-profits and Not-for-profit institutions; Number of Respondents: 51; Total Annual Responses: 612; Total Annual Hours: 612. (For policy questions regarding this collection contact Roland Herrera at 410-786-0668.)

14. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Annual Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Participation Report; Use: The collected baseline data is used to assess the effectiveness of state early and periodic screening, diagnostic and treatment (EPSDT) programs in reaching eligible children (by age group and basis of Medicaid eligibility) who are provided initial and periodic child health screening services, referred for corrective treatment, and receiving dental, hearing, and vision services. This assessment is coupled with the state's results in attaining the participation goals set for the state. The information gathered from this report, permits federal and state managers to evaluate the effectiveness of the EPSDT law on the basic aspects of the program. Form Number: CMS-416 (OMB control number 0938-0354); Frequency: Yearly and on occasion; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 56; Total Annual Responses: 168; Total Annual Hours: 1,624. (For

policy questions regarding this collection contact Kimberly Perrault at 410-786-2482.)

15. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Programs for All-inclusive Care of the Elderly (PACE) and Supporting Regulations in 42 CFR Part 460; Use: This information collection addresses all operational components of the PACE program (as defined in 42 CFR part 460) with the exception of the application process (§460.12). We are removing the application requirements and burden since this CMS-R-244 package is lengthy and we recognize that it can be somewhat time consuming to review. We believe the change will help streamline the public and OMB's review of the application as well as the remaining requirements and burden under the CMS-R-244 package.

The application is being moved under a new information collection request with a new CMS identification number (CMS-10631). An OMB control number specific to the application process is pending. The CMS-10631 information collection request was submitted to OMB on October 6, 2016, under ICR Reference No: 201610-0938-001. When approved, the control number can be found on www.reginfo.gov/public/.

Form Number: CMS-R-244 (OMB control number: 0938-0790); Frequency: Once and occasionally; Affected Public: Private sector (Business or other for-profits and Not-for-profit institutions); Number of Respondents: 130; Total Annual Responses: 145,455; Total Annual Hours: 61,350. (For policy questions regarding this collection contact Debbie Van Hoven at 410-786-6625).

16. Type of Information Collection Request: Extension of a currently approved collection;
Title of Information Collection: Healthcare Effectiveness Data and Information Set (HEDIS®)
Data Collection for Medicare Advantage; Use: We use the collected data to: monitor Medicare
Advantage organization performance, inform audit strategies, and inform beneficiary choice
through their display in our consumer-oriented public compare tools and Web sites. Medicare
Advantage organizations use the data for quality assessment and as part of their quality
improvement programs and activities. Quality Improvement Organizations and our contractors
use HEDIS® data in conjunction with their statutory authority to improve quality of care.
Consumers use the information to help make informed health care choices. In addition, the data
is made available to researchers and others as public use files at www.cms.hhs.gov. Form
Number: CMS-10219 (OMB control number: 0938-1028); Frequency: Yearly; Affected Public:
Business or other for-profit and Not-for-profit institutions; Number of Respondents: 576; Total
Annual Responses: 576; Total Annual Hours: 184,320. (For policy questions regarding this
collection contact Lori Teichman at 410-786-6684.)

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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