

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|-----------------------------------|-------------------------|-----------------------|------------------------------------|--|-------------------------|
| Public Health Laboratorians | Special Data Call | 136 | 1 | 30/60 | 68 |
| Total | | | | | 68 |

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019-22732 Filed 10-17-19; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-10344]

Agency Information Collection Activities: Proposed Collection; Comment Request; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Correction of notice.

SUMMARY: This document corrects the information provided for [Document Identifier: CMS-10344] titled “Elimination of Cost-Sharing for Full Benefit Dual Eligible Individuals Receiving Home and Community-Based Services.”

FOR FURTHER INFORMATION CONTACT: William N. Parham, III, (410) 786-4669.

SUPPLEMENTARY INFORMATION:

I. Background

In the September 25, 2019, issue of the **Federal Register** (84 FR 50453), we published a Paperwork Reduction Act notice requesting a 60-day public comment period for the information collection request identified under CMS-10344, OMB control number 0938-1127, and titled “Elimination of Cost-Sharing for Full Benefit Dual Eligible Individuals Receiving Home and Community-Based Services.”

II. Explanation of Error

In the September 25, 2019, notice, the information provided in the first column, at the end of the second paragraph, on page 50455, was published with incorrect information in the “*For policy questions*” section. This notice corrects the language found in the “*For policy questions*” section in the first column, at the end of the second paragraph, on page 50455 of the

September 25th notice. All of the other information contained in the September 25, 2019, notice is correct. The related public comment period remains in effect and ends November 25, 2019.

III. Correction of Error

In FR Doc. 2019-20858 of September 25, 2019 (84 FR 50453), page 50455, the language in the first column, at the end of the second paragraph begins with “[For policy questions and ends with “at 410-786-0668],” is corrected to read as follows:

[For policy questions regarding this collection contact Roland O. Herrera at 410-786-0668.]

Dated: October 11, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019-22726 Filed 10-17-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS-10227, CMS-10243, CMS-10316 and CMS-10716]

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 (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 December 17, 2019.

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’ website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

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 N. Parham at (410) 786-4669.

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-10227 PACE State Plan

Amendment Preprint

CMS-10243 Testing Experience and Functional Tools: Functional Assessment Standardized Items (FASI) Based on the CARE Tool

CMS-10316 Implementation of the Medicare Prescription Drug Plan (PDP) and Medicare Advantage (MA) Plan Disenrollment Reasons Survey

CMS-10716 Applicable Integrated Plan Coverage Decision Letter

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: Revision 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.)

2. Type of Information Collection
Request: Extension of a currently approved collection; *Title of Information Collection:* Testing Experience and Functional Tools: Functional Assessment Standardized Items (FASI) Based on the CARE Tool; *Use:* In 2012, CMS funded a project entitled, Technical Assistance to States for Testing Experience and Functional Tools (TEFT) Grants. One component of this demonstration is to amend and test the reliability of a setting-agnostic, interoperable set of data elements, called “items,” that can support standardized assessment of individuals across the continuum of care. Items that were created for use in post-acute care settings using the Continuity Assessment Record and Evaluation (CARE) tool have been adopted, modified, or supplemented for use in community-based long-term services and supports (CB-LTSS) programs. This project will test the reliability and validity of the function-related assessment items, now referred to as Functional Assessment Standardized Items (FASI), when applied in community settings, and in various populations: Elders (65 years and older); younger adults (18–64) with physical disabilities; and adults of any age with intellectual or developmental disabilities, with severe mental illness, or with traumatic brain injury.

Individual-level data will be collected two times using the TEFT FASI Item Set. The first data collection effort will collect data that can be analyzed to evaluate the reliability and validity of the FASI items when used with the five waiver populations. Assessors will conduct functional assessments in client homes using the TEFT FASI Item Set. Changes may be recommended to individual TEFT FASI items, to be made prior to releasing the TEFT FASI items for use by the states. The FASI Field Test Report will be released to the public.

The second data collection will be conducted by the states to demonstrate their use of the FASI data elements. The assessment data could be used by the states for multiple purposes. They may use the standardized items to determine individual eligibility for state programs, or to help determine levels of care within which people can receive services, or other purposes. In the second round of data collection, states will demonstrate their proposed uses, manage their FASI data collection and conduct their own analysis, to the extent they propose to do such tasks. The states have been funded under the

demonstration grant to conduct the round 2 data collection and analysis. These states will submit reports to CMS describing their experience in the Round 2 data collection, including the items they collected, how they planned to use the data, and the types of challenges and successes they encountered in doing so. The reports may be used by CMS in their evaluation of the TEFT grants. *Form Number:* CMS-10243 (OMB control number: 0938-1037); *Frequency:* On occasion; *Affected Public:* Individuals and Households; *Number of Respondents:* 5,650; *Total Annual Responses:* 5,650; *Total Annual Hours:* 2,825. (For policy questions regarding this collection contact Kerry Lida at 410-786-4826.)

3. Type of Information Collection
Request: Revision of a currently approved collection; *Title of Information Collection:* Implementation of the Medicare Prescription Drug Plan (PDP) and Medicare Advantage (MA) Plan Disenrollment Reasons Survey; *Use:* The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provides a requirement to collect and report performance data for Part D prescription drug plans. Specifically, the MMA under Sec. 1860D-4 (Information to Facilitate Enrollment) requires CMS to conduct consumer satisfaction surveys regarding the PDP and MA contracts pursuant to section 1860D-4(d).

The Centers for Medicare & Medicaid Services (CMS) developed the Disenrollment Survey to capture the reasons for disenrollment at a time that is as close as possible to the actual date of disenrollment. Through this survey, CMS seeks to: (1) Obtain information about beneficiaries' expectations relative to provided benefits and services (for both MA and PDPs) and (2) determine the reasons that prompt beneficiaries to voluntarily disenroll. It is important to include such information from disenrollees as CMS assesses plan performance, because plan disenrollment can be a broad indicator of beneficiary dissatisfaction with some aspect of plan services, such as access to care, customer service, cost, benefits provided, or quality of care. Information obtained from the Disenrollment Survey also supports the quality improvement efforts of individual plans and provides data to assist consumer choice through use of the Medicare Plan Finder website.

The survey results are an important plan monitoring tool for CMS to ensure that Medicare beneficiaries are receiving high quality services from contracted providers. CMS uses information from the survey to track changes in the

reasons Medicare beneficiaries cite for disenrolling to monitor improvements/declines over time nationally and at the plan level. CMS also uses the disenrollment survey results to support the quality improvement efforts of individual plans, by providing plans with a detailed, annual report showing the reasons disenrollees cited for voluntarily leaving the plan and comparing the plan's scores to regional and national benchmarks. Additionally, CMS uses the plan-specific results of the survey to provide Medicare beneficiaries with information (*i.e.*, reasons cited for disenrolling from a plan and the frequency with which disenrollees cite each of the reasons) to assist beneficiaries with their annual consumer choice of plans. *Form Number:* CMS-10316 (OMB control number: 0938-1113); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 43,872; *Total Annual Responses:* 43,872; *Total Annual Hours:* 8,774. (For policy questions regarding this collection contact Beth Simon at 415-744-3780.)

4. *Type of Information Collection Request:* New Collection (Request for a new OMB control number); *Title of Information Collection:* Applicable Integrated Plan Coverage Decision Letter; *Use:* The Bipartisan Budget Act (BBA) of 2018 directed the establishment of procedures to unify Medicare and Medicaid grievance and appeals procedures to the extent feasible for dual eligible special needs plans (D-SNPs) beginning in 2021. On April 16, 2019, CMS finalized rules (hereafter referred to as the April 2019 final rule) to implement these new statutory provisions.[1] As a result of these regulations, starting in 2021, a subset of full integrated dual special needs plans (FIDE SNPs) and highly integrated dual special needs plans (HIDE SNPs) will need to unify and update appeals and grievance procedures, including how enrollees are notified of their appeal rights.

Applicable integrated plans as defined at § 422.561 are required to issue form CMS-10716 when a request for either a medical service or payment covered under the Medicare or Medicaid benefit is denied in whole or in part. The notice explains why the plan denied the service or payment and informs the plan enrollees of their appeal rights.

The "Applicable Integrated Plan Coverage Decision Letter" or the "coverage decision letter", which will be issued as a result of an integrated organization determination under 42 CFR 422.631 when an applicable

integrated plan reduces, stops, suspends, or denies, in whole or in part, a request for a service/item (including a Part B drug) or a request for payment of a service/item (including a Part B drug) the member has already received. "Applicable integrated plans," hereinafter referred to as "plans", are defined at 42 CFR 422.561 as FIDE SNPs or HIDE SNPs with exclusively aligned enrollment, where state policy limits the D-SNP's membership to a Medicaid managed care plan offered by the same organization. Applicable integrated plans will issue the coverage decision letter starting in CY 2021 in place of the Notice of Denial of Medical Coverage (or Payment) (NDMCP) form (CMS-10003) as part of requirements to unify appeals and grievance processes. All other Medicare Advantage (MA) plans will continue to use the NDMCP form (CMS-10003). *Form Number:* CMS-10716 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 693; *Total Annual Responses:* 693; *Total Annual Hours:* 116. (For policy questions regarding this collection contact Marna Metcalf Akbar at 410-786-8251.)

Dated: October 11, 2019.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019-22718 Filed 10-17-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS-576A]

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 November 18, 2019.

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:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>

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

2. 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