

beneficiary does not complete this additional information.

With the long-term goal of collecting race and ethnicity data from all Medicare beneficiaries, CMS will focus initial efforts on beneficiaries who newly elect or change coverage in the Medicare Part C and D program. The detailed race and ethnicity categories collected through the demographic pilot on the enrollment form will be compliant with the 2011 HHS Data Collection Standards to provide granular information for plans and CMS to understand the diversity of the beneficiary population. The data will be used to: (1) Explore the response rate to race and ethnicity questions as a whole and how it intersects with beneficiary income and other demographics; (2) Conduct focus groups, to be approved in a separate PRA package, among non-responders to the race and ethnicity questions to understand how people who elect to not respond to the race and ethnicity questions perceive the addition of those questions on the form; (3) Continue to test CMS' race and ethnicity imputation models by adding additional race and ethnicity data to the data CMS already has; and (4) Determine the data necessary for sufficient samples sizes to conduct analyses of disaggregated race and ethnicity categories. As part of a broader health equity effort, CMS has interest in identifying patterns of differences across many key process and care outcomes by sociodemographic characteristics, including race and ethnicity. To best characterize these differences, self-reported *and* granular data are needed. Collecting these data will support efforts to continue to strengthen, for example, CMS OMH's stratified reporting efforts, which currently *do* consider quality indicators by race and ethnicity, but at present these data are *not* granular and *not* self-reported. In addition, this data will allow us to validate imputation methods CMS currently uses for race and ethnicity, to ensure that we do not rely on methodologies that unintentionally create or exacerbate disparities. To assess readiness for analysis of collected data (particularly with regard to considering sample sizes, especially of small groups), continual assessment will be required—simultaneously as enrollment happens—because readiness will depend partly on distribution of responses to these items by enrollees.

These categories are of great interest to CMS and will improve the accuracy of current data sets. We acknowledge that it may take several years of data collection to conduct other meaningful studies CMS intends to pursue that are

not listed above. In addition to the aforementioned uses, CMS will ultimately use this information to: Track beneficiary enrollment, including tracking patterns in enrollment by race and ethnicity over time; to identify, monitor, and develop effective and efficient strategies and incentives to reduce and eliminate health and health care inequities; to validate existing race and ethnicity imputation methods; and to ensure that clinically appropriate and equitable care (in terms of payment, access, and quality) is consistently provided to all beneficiaries. *Form Number:* CMS-10718 (OMB control number: 0938-1378); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments, Federal Government, Private Sector (Business or other for-profits and Not-for-profits); *Number of Respondents:* 80,539,628; *Number of Responses:* 80,539,628; *Total Annual Hours:* 8,567,975. (For questions regarding this collection contact Deme Umo at (410) 786-8854.)

Dated: May 2, 2022.

William N. Parham, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-265-11, CMS-10544, CMS-10338, and CMS-10599]

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

AGENCY: Centers for Medicare & Medicaid Services, Health and Human 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 June 6, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

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>.

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. 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:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Independent Renal Dialysis Facility Cost Report; *Use:* Under the authority of sections 1815(a)

and 1833(e) of the Act, CMS requires that providers of services participating in the Medicare program submit information to determine costs for health care services rendered to Medicare beneficiaries. CMS requires that providers follow reasonable cost principles under 1861(v)(1)(A) of the Act when completing the Medicare cost report (MCR). Regulations at 42 CFR 413.20 and 413.24 require that providers submit acceptable cost reports on an annual basis and maintain sufficient financial records and statistical data, capable of verification by qualified auditors.

ESRD facilities participating in the Medicare program submit these cost reports annually to report cost and statistical data used by CMS to determine reasonable costs incurred for furnishing dialysis services to Medicare beneficiaries and to effect the year-end cost settlement for Medicare bad debts. *Form Number:* CMS-265-11 (OMB control number: 0938-0236); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits, State, Local, or Tribal Governments); *Number of Respondents:* 7,492; *Total Annual Responses:* 7,492; *Total Annual Hours:* 494,472. (For questions regarding this collection contact Keplinger, Jill C. at 410-786-4550.)

2. Type of Information Collection Request: Reinstatement without change of a previously approved collection; *Title of Information Collection:* Good Cause Processes; *Use:* Section 1851(g)(3)(B)(i) of the Act provides that MA organizations may terminate the enrollment of individuals who fail to pay basic and supplemental premiums after a grace period established by the plan. Section 1860D-1(b)(1)(B)(v) of the Act generally directs us to establish rules related to enrollment, disenrollment, and termination for Part D plan sponsors that are similar to those established for MA organizations under section 1851 of the Act. Consistent with these sections of the Act, subpart B in each of the Parts C and D regulations sets forth requirements with respect to involuntary disenrollment procedures at 42 CFR 422.74 and 423.44, respectively. In addition, section 1876(c)(3)(B) establishes that individuals may be disenrolled from coverage as specified in regulations. Thus, current regulations at 42 CFR 417.460 specify that a cost plan, specifically a Health Maintenance Organization (HMO) or competitive medical plan (CMP), may disenroll a member who fails to pay premiums or other charges imposed by the plan for deductible and coinsurance amounts.

These good cause provisions authorize CMS to reinstate a disenrolled

individual's enrollment without interruption in coverage if the non-payment is due to circumstances that the individual could not reasonably foresee or could not control, such as an unexpected hospitalization. At its inception, the process of accepting, reviewing, and processing beneficiary requests for reinstatement for good cause was carried out exclusively by CMS. *Form Number:* CMS-10544 (OMB control number: 0938-1271); *Frequency:* Annually; *Affected Public:* Business or other for-profits State, Local, or Tribal Governments); *Number of Respondents:* 312; *Total Annual Responses:* 41,289; *Total Annual Hours:* 27,499. (For questions regarding this collection contact Ronke Fabayo at (410) 786-4460.)

3. Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Affordable Care Act Internal Claims and Appeals and External Review Procedures for Non-grandfathered Group Health Plans and Issuers and Individual Market Issuers; *Use:* The information collection requirements ensure that claimants receive adequate information regarding the plan's claims procedures and the plan's handling of specific benefit claims. Claimants need to understand plan procedures and plan decisions in order to appropriately request benefits and/or appeal benefit denials. The information collected in connection with the HHS-administered federal external review process is collected by HHS, and is used to provide claimants with an independent external review. *Form Number:* CMS-10338 (OMB control number: 0938-1099); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 497,262; *Total Annual Responses:* 517,014,153; *Total Annual Hours:* 1,198,692. (For policy questions regarding this collection contact Laura Byabazaire at 301-492-4128.)

4. Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Review Choice Demonstration for Home Health Services; *Use:* Section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1(a)(1)(J)) authorizes 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 (the Act)." Pursuant to this authority, the CMS seeks to develop and implement a Medicare demonstration project, which

CMS believes will help assist in developing improved procedures for the identification, investigation, and prosecution of Medicare fraud occurring among Home Health Agencies (HHA) providing services to Medicare beneficiaries.

This revised demonstration helps assist in developing improved procedures for the identification, investigation, and prosecution of potential Medicare fraud. The demonstration helps make sure that payments for home health services are appropriate through either pre-claim or postpayment review, thereby working towards the prevention and identification of potential fraud, waste, and abuse; the protection of Medicare Trust Funds from improper payments; and the reduction of Medicare appeals. CMS has implemented the demonstration in Illinois, Ohio, North Carolina, Florida, and Texas with the option to expand to other states in the Palmetto/JM jurisdiction. Under this demonstration, CMS offers choices for providers to demonstrate their compliance with CMS' home health policies. Providers in the demonstration states may participate in either 100 percent pre-claim review or 100 percent post payment review. These providers will continue to be subject to a review method until the HHA reaches the target affirmation or claim approval rate. Once an HHA reaches the target pre-claim review affirmation or post-payment review claim approval rate, it may choose to be relieved from claim reviews, except for a spot check of their claims to ensure continued compliance. Providers who do not wish to participate in either 100 percent pre-claim or post payment reviews have the option to furnish home health services and submit the associated claim for payment without undergoing such reviews; however, they will receive a 25 percent payment reduction on all claims submitted for home health services and may be eligible for review by the Recovery Audit Contractors.

The information required under this collection is required by Medicare contractors to determine proper payment or if there is a suspicion of fraud. Under the pre-claim review option, the HHA sends the pre-claim review request along with all required documentation to the Medicare contractor for review prior to submitting the final claim for payment. If a claim is submitted without a pre-claim review decision one file, the Medicare contractor will request the information from the HHA to determine if payment is appropriate. For the post payment review option, the Medicare contractor

will also request the information from the HHA provider who submitted the claim for payment from the Medicare program to determine if payment was appropriate. *Form Number:* CMS-10599 (OMB control number: 0938-1311); *Frequency:* Frequently, until the HHA reaches the target affirmation or claim approval threshold and then occasionally; *Affected Public:* Private Sector (Business or other for-profits and Not-for-profits); *Number of Respondents:* 3,631; *Number of Responses:* 1,467,243; *Total Annual Hours:* 7,445,143. (For questions regarding this collection contact Jennifer McMullen (410)786-7635.)

Dated: April 29, 2022.

William N. Parham, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity: National Medical Support Notice Part A (OMB No.: 0970-0222)

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF), is requesting a 3-year extension of the National Medical Support Notice (NMSN) Part A. This request includes minor revisions to the NMSN Part A form, revisions to and separation of the instructions into a stand-alone attachment, a Part A sample, and the addition of the State Medical Support Contacts and Program Requirements matrix. The current Office of Management and Budget (OMB) approval expires on October 31, 2022.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Federal law requires that all child support orders under Title IV-D of the Social Security Act include medical coverage. The Child Support Performance and Incentive Act of 1998 (CSPIA) requires enforcement of this

provision; the NMSN Part A is the means to enforce health care orders.

This information collection expedites requests for medical coverage between state child support enforcement agencies and employers. OCSE maintains Part A of the NMSN, which states initiate and send to a parent's employer to complete. States must supply some sensitive information to the parent's employer in order to enroll the child(ren) in the correct health coverage plan. This information includes names, dates of birth, Social Security numbers, and addresses. The employer retains the income withholding part of the form and withholds from the employee's income any premium payments the health care plan may require. Then, the employer's health care administrator enrolls the child(ren) in the health care plan. The Department of Labor (DOL) maintains Part B of the NMSN. This request includes minor revisions to the NMSN Part A form, revisions to and separation of the instructions into a stand-alone attachment, a Part A sample, and the addition of the State Medical Support Contacts and Program Requirements matrix. OCSE will also request from OMB that the NMSN Part A expiration date match the expiration date of the NMSN Part B, which will be submitted by DOL.

Respondents: States and employers.

ANNUAL BURDEN ESTIMATES

Information collections	Respondent	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
National Medical Support Notice Part A and Instructions. State Medical Support Contacts and Program Requirements Matrix.	States	54	90,194	.17	827,981
	Employers	1,310,727	3.72	.17	828,904
	States	54	1	1	54

Estimated Total Annual Burden Hours: 1,656,939.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques

or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 45 U.S.C. 303.32; the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Public Law 104-193; CSPIA, Pub. L. 105-200, Sec. 401(c); Sec. 609(a)(5)(C) of the Employee Retirement Income Security Act of 1974.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0621]

Advisory Committee; Anesthetic and Analgesic Drug Products Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the