

receive care and administrative datasets such as vital records and hospital discharge data. While MDs are rare genetic diseases with an estimated prevalence of 16.1/100,000, they have a high impact on affected individuals, their families, and society. MDs can be classified into nine major groups: Duchenne muscular dystrophy (DMD), Becker muscular dystrophy (BMD), myotonic dystrophy (DM), facioscapulohumeral muscular dystrophy (FSHD), limb-girdle muscular dystrophy (LGMD), congenital muscular dystrophy (CMD), Emery-Dreifuss muscular dystrophy (EDMD), and distal MD. A recent MD STARnet study has estimated the combined prevalence for DMD and BMD to be 1.92–2.48/10,000

males age 5–9 years old. MD STARnet aims to improve understanding of MDs and ultimately the quality of life of people and their families living with MD. Individuals with MDs frequently report pain and fatigue, but studies have largely been conducted in clinic-based populations and included the three most common MDs. Population-based studies are needed to describe the frequency and management of pain and fatigue and their impact on the lives of individuals with various types of MD.

The purpose of the proposed study is to describe the epidemiology of COVID-19 and flu and the experience with pain, fatigue, pregnancy, and infertility for adults living with MD who are identified through MD STARnet. Results

generated from the study will provide a better understanding of: (1) the occurrence, testing, treatment and severity of COVID-19 in relation to MD; (2) vaccination status and reasons for not receiving COVID-19 and flu vaccinations; (3) the frequency, intensity, and management of pain and fatigue; and (4) the effect of having MD on pregnancy and fertility on adults living with MD. Ultimately, this information can be used to develop interventions that improve the lives of people with MD and their families.

CDC requests OMB approval for an estimated 974 annual burden hours. There are no costs to respondents other than their time to participate.

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 hours |
|---------------------------------|-----------------------------------|-----------------------|------------------------------------|--|--------------------|
| Adult males 18 and over | MD STARnet Male Questionnaire ... | 1,794 | 1 | 15/60 | 449 |
| Adult females 18 and over | MD STARnet Female Questionnaire | 1,574 | 1 | 20/60 | 525 |
| Total | | | | | 974 |

Jeffrey M. Zirger,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10146]

Agency Information Collection Activities: Proposed Collection; 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 (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 November 22, 2022.

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, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

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-10146 Notice of Denial of Medicare Prescription Drug 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:* Notice of Denial of Medicare Prescription Drug Coverage; *Use:* Part D plan sponsors are required to issue the Notice of Denial of Medicare Prescription Drug Coverage notice when a request for a prescription drug or payment is denied, in whole or in part. The written notice must include a statement, in understandable language, the reasons for the denial and a description of the appeals process.

The purpose of this notice is to provide information to enrollees when prescription drug coverage has been denied, in whole or in part, by their Part D plans. The notice must be readable, understandable, and state the specific reasons for the denial. The notice must also remind enrollees about their rights and protections related to requests for prescription drug coverage and include an explanation of both the standard and expedited redetermination processes and the rest of the appeal process. *Form Number:* CMS-10146 (OMB control number 0938-0973); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits); *Number of Respondents:* 683; *Number of Responses:* 2,627,898; *Total Annual Hours:* 656,975. (For policy questions regarding this collection contact Coretta Edmondson at 410-786-0512).

Dated: September 19, 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 Identifier CMS-643]

Agency Information Collection Activities: Proposed Collection; 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 (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 November 22, 2022.

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, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

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-643 Hospice Survey and Deficiencies Report Form and Supporting Regulations

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:* Hospice Survey and Deficiencies Report Form and Supporting Regulations; *Use:* We use the information collected as the basis for certification decisions for hospices that wish to obtain or retain participation in the Medicare and Medicaid programs. The information is used by CMS regional offices, which have the delegated authority to certify Medicare facilities for participation, and by State Medicaid agencies, which have comparable authority under Medicaid. The information on the Hospice Survey and Deficiencies Report Form is coded