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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers CMS-10825]

#### 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 *March 8, 2023*.

**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](http://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, 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 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:* New collection (Request for a new OMB control number); *Title of Information Collection:* List of Screening Instruments for Housing Stability, Food Security, and Transportation Questions on Health Risk Assessments; *Use:* This information collection request is for the new regulation at 42 CFR 422.101(f)(1)(i) requiring that all MA SNP health risk assessments (HRAs) include at least one question from a list of screening instruments specified by CMS in sub-regulatory guidance on each of three domains (housing stability, food security, and access to transportation) beginning in CY 2024. This new requirement will help better identify the risk factors that may inhibit enrollees from accessing care and achieving optimal health outcomes and independence and enable MA SNPs to take these risk factors into account in enrollee individualized care plans. This information collection request provides the list of CMS-specified Social Determinants of Health (SDOH) screening instruments available for SNPs to meet the new requirement.

We note that the scope of the information collection currently approved under OMB control number 0938-1422 (CMS-10799) listed in the

January 2022 proposed rule was too broad to include a discussion of the new regulation at 42 CFR 422.101(f)(1)(i) and the information collection requirements contained therein. Also, we did not finalize our proposal to require SNPs to use a standardized set of questions based on comments received from on the January 2022 proposed rule titled "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs" (87 FR 1842). Therefore, in accordance with the implementing regulations of the PRA at 5 CFR 1320, we did not include this information collection in OMB control number 0938-1422 (CMS-10799) and are conducting a standard PRA clearance process to obtain public comment on the list of SDOH screening instruments described in the May 2022 final rule.

CMS received eight comments from eight different organizations. CMS has included responses to these comments as well as a crosswalk of the changes that CMS has made to its guidance document as a result of the comments received. In response to these comments, we made two minor revisions to our guidance document to clarify circumstances in which SNPs may use a state-required screening instrument as well as to encourage states with non-standardized state-specific screening instruments to begin the process of creating health IT coding for them. *Form Number:* CMS-10731 (OMB control number: 0938-New); *Frequency:* Occasionally; *Affected Public:* Private sector (business or other for-profits); *Number of Respondents:* 174; *Total Annual Responses:* 174; *Total Annual Hours:* 167. (For policy questions regarding this collection contact Michelle Conway at 202-260-7752.)

Dated: January 31, 2023.

**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

### Food and Drug Administration

[Docket No. FDA-2019-E-1972]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; OLUMIANT

**AGENCY:** Food and Drug Administration, HHS.