

0215, Exp. 3/31/2023)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C.), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability of the population of the United States.

The National Death Index (NDI) is a database containing identifying death record information submitted annually to NCHS by all the jurisdiction (states and territories) vital statistics offices, beginning with deaths in 1979. Searches

against the NDI file provide the jurisdictions and dates of death, and the death certificate numbers of deceased study subjects. Using the NDI Plus service, researchers have the option of also receiving cause of death information for deceased subjects, thus reducing the need to request copies of death certificates from the jurisdictions. The NDI Plus option currently provides the International Classification of Disease (ICD) codes for the underlying and multiple causes of death for the years 1979–2021. Health researchers must complete administrative forms in order to apply for NDI services and submit records of study subjects for computer matching against the NDI file.

A three-year revision request is submitted to continue the use of the two

administrative forms (the application form and transmittal form) utilized in the operation of the National Death Index (NDI) program, along with worksheets used to calculate related fees. These forms are submitted by NDI users when applying for use of the NDI and when actually using the service. In addition, this request includes the electronic versions that replace the three paper documents, one of which will include a minor reduction in the number of data collection items.

The total estimated annual burden hours are 1,276. This represents an increase of 489 hours from 787, due primarily to the increase in applications, and transmittal forms. There is no cost to respondents except for their time.

ESTIMATES OF ANNUALIZED BURDEN HOURS

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|--------------------|-----------------------------------------------|-----------------------|------------------------------------|----------------------------------------|
| Researcher | Application Form—Electronic | 282 | 1 | 150/60 |
| Researcher | Transmittal Form—Paper/Electronic | 400 | 3 | 18/60 |
| Researcher | Early Transmittal Form—Paper/Electronic | 100 | 3 | 18/60 |
| Researcher | Fee Worksheet | 450 | 1 | 15/60 |
| Researcher | Early Release Fee Worksheet | 100 | 1 | 5/60 |

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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The meeting is being amended to change the meeting time and should read as follows:

Date: March 8, 2023.

Time: 10:00 a.m.–3:00 p.m., EST.

The meeting is closed to the public.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–23–22HK]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “Surveillance of HIV-related service barriers among Individuals with Early or Late HIV Diagnoses (SHIELD)” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on July 22, 2022, to obtain comments from the public and affected agencies. CDC received no comments to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—DP23-002, Improving Health Outcomes for Patients With Inflammatory Bowel Disease; Amended Notice of Closed Meeting

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—DP23-002, Improving Health Outcomes for Patients with Inflammatory Bowel Disease; March 8, 2023, 11:00 a.m.–3:00 p.m., EST, Teleconference, in the original FRN. The meeting was published in the **Federal Register** on December 9, 2022, Volume 87, Number 236, page 75632.

FOR FURTHER INFORMATION CONTACT:

Catherine Barrett, Ph.D., Scientific Review Officer, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway, Mailstop S107-3, Atlanta, Georgia 30341-3717; Telephone: (404) 718-7664; Email: CBarrett@cdc.gov.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023-02476 Filed 2-3-23; 8:45 am]

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(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Surveillance of HIV-related service barriers among Individuals with Early or Late HIV Diagnoses (SHIELD)—New—National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

National HIV Surveillance System (NHSS) data indicate that 36,940 adolescents and adults received an HIV diagnosis in the United States and dependent areas in 2019. During 2015–2019, the overall rate of annual diagnoses decreased only slightly, from 12.4 to 11.1 per 100,000. Although not every jurisdiction reports complete laboratory data needed to identify the stage of infection, data from the majority of jurisdictions show that many of these cases were classified as Stage 0 (6.9%) or Stage 3 (21.5%) infection (i.e., cases diagnosed in early infection or late infection, respectively). Early and late diagnoses represent recent failures in prevention and testing systems, respectively, and opportunities to understand needed improvements in these systems.

The NHSS would classify HIV infections as Stage 0 if the first positive HIV test were within six months of a negative HIV test. Persons who received a diagnosis at Stage 0 (i.e., early diagnosis) could access HIV testing shortly after infection yet could not benefit from biomedical and behavioral interventions to prevent HIV infection.

The federal Ending the HIV Epidemic in the U.S. (EHE) initiative prioritizes the provision of HIV preexposure prophylaxis (PrEP), syringe services programs, treatment as prevention efforts, and other proven interventions—as part of the Prevent

pillar of the EHE initiative—to prevent new HIV infections.

HIV infections are classified as Stage 3 (AIDS) by the presence of an AIDS-defining opportunistic infection or by the lowest CD4 lymphocyte test result. Persons with Stage 3 infection at the time of their initial HIV diagnosis (i.e., late diagnosis) did not benefit from timely receipt of testing or HIV prevention interventions. They were likely unaware of their infection for a substantial length of time.

Nationally, an estimated 13.3% of persons with HIV are unaware of their infection, contributing to an estimated 40% of all ongoing transmission. Increasing early diagnosis is a crucial pillar of efforts to end HIV in the United States.

Given the continued occurrence of HIV infections in the United States, the barriers and gaps associated with low uptake of HIV testing and prevention services must be addressed to reduce new infections and facilitate timely diagnosis and treatment. Individual- and systems-level factors likely contribute to barriers and gaps in testing and prevention. Therefore, CDC is sponsoring this data collection to improve understanding of barriers and gaps associated with new infection and late diagnosis in the era of multiple testing modalities and prevention options such as PrEP. These enhanced surveillance activities will identify actionable missed opportunities for early diagnosis and prevention, thus informing allocation of resources, development and prioritization of interventions, and evidence-based local and national decisions to improve HIV testing and address prevention gaps.

CDC requests OMB approval for an estimated 2,916 annual burden hours. There are no costs to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|--------------------------------------|----------------------------------|-----------------------|------------------------------------|----------------------------------------|
| Potential Eligible Participant | Recruitment Script English | 2,000 | 1 | 15/60 |
| Potential Eligible Participant | Recruitment Script Spanish | 500 | 1 | 15/60 |
| Eligible Participant | Consent—English | 2,000 | 1 | 5/60 |
| Eligible Participant | Consent—Spanish | 500 | 1 | 5/60 |
| Eligible Participant | Survey—English | 2,000 | 1 | 50/60 |
| Eligible Participant | Survey—Spanish | 500 | 1 | 50/60 |

Jeffrey M. Zirger,

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

[FR Doc. 2023-02420 Filed 2-3-23; 8:45 am]

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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. 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.

[FR Doc. 2023-02369 Filed 2-3-23; 8:45 am]

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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.