

www.cdc.gov/niosh/nora/crosssectors/ti/agenda.html.

FOR FURTHER INFORMATION CONTACT:

Emily Novicki, M.A., M.P.H., (NORACoordinator@cdc.gov), National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Mailstop E-20, 1600 Clifton Road NE, Atlanta, GA 30329, phone (404) 498-2581 (not a toll free number).

SUPPLEMENTARY INFORMATION:

On December 7, 2017, NIOSH published a request for public review in the **Federal Register** [82 FR 57758] of the draft version of the *National Occupational Research Agenda for Traumatic Injury Prevention*. All comments received were reviewed and addressed where appropriate.

Dated: August 22, 2018.

Frank J. Hearl,

Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-18-1080]

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 [HIV Outpatient Study (HOPS)] 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 [September 26, 2017] to obtain comments from the public and affected agencies. CDC received [2] comments related 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:

(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 or send an email to omb@cdc.gov. 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

HIV Outpatient Study (HOPS) (OMB Control Number 0920-1080, Expiration Date 08/31/2018)—REVISION—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention requests a three year approval for the HIV Outpatient Study data collection activity. The HIV Outpatient Study (HOPS) is a prospective longitudinal cohort of HIV-infected outpatients at eight well-established private HIV care practices and university-based U.S. clinics. Clinical data are abstracted on ongoing basis from the medical records of adult HIV-infected HOPS study participants, who also complete an optional seven minute telephone/web-based behavioral assessment as part of their annual clinic visit. Before enrolling in this study, all potential study participants will undergo an informed consent process (including signing of a written informed consent) which is estimated to take 15 minutes.

The core areas of HOPS research extending through the present HIV treatment era include (i) monitoring death rates and causes of death (ii) characterizing the optimal patient

management strategies to reduce HIV-related morbidity and mortality (e.g., effectiveness of antiretroviral therapies and other clinical interventions (iii) monitoring of sexual and drug use behaviors to inform Prevention with Positives, and (iv) investigating disparities in the HIV care continuum by various demographic factors. In recent years, the HOPS has been instrumental in bringing attention to emerging issues in chronic HIV infection with actionable opportunities for prevention, including: Cardiovascular disease, fragility fractures, renal and hepatic disease, and cancers. The HOPS remains an important source for multi-year trend data concerning conditions and behaviors for which data are not readily available elsewhere, including: Rates of opportunistic illnesses, rates of comorbid conditions (e.g., hypertension, obesity, diabetes) and antiretroviral drug resistance.

Data will be collected through medical record abstraction by trained abstractors and by telephone or internet-based, computer-assisted interviews at eight funded study sites in six U.S. cities. Collection of data abstracted from patient medical records provides data in five general categories: Demographics and risk behaviors for HIV infection; symptoms; diagnosed conditions (definitive and presumptive); medications prescribed (including dose, duration, and reasons for stopping); all laboratory values, including CD4+ T-lymphocyte (CD4+) cell counts, plasma HIV-RNA determinations, and genotype, phenotype, and trophile results. Data on visit frequency, AIDS, and death are acquired from the clinic chart.

Data collected using a brief Telephone Audio-Computer Assisted Self-Interview (T-ACASI) survey or an identical web-based Audio-Computer Assisted Self-Interview (ACASI) include: age, sex at birth, use of alcohol and drugs, cigarette smoking, adherence to antiretroviral medications, types of sexual intercourse, condom use, and disclosure of HIV status to partners.

We estimate consenting 450 new participants per year across all HOPS study sites (50 participants at each of the eight sites). The consent process takes approximately 15 minutes to complete. Medical record abstractions will be completed on all eligible participants. All eligible participants will be offered the opportunity to participate in an optional short survey that will take approximately seven minutes. Participation of respondents is voluntary. There is no cost to the

respondents other than their time. The estimated annual burden hours are 405.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
HOPS study Patients	Behavioral survey (att 3a,b,9)	2,500	1	7/60
HOPS Study Patients	Consent form (att 4)	450	1	15/60

Jeffrey M. Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-10137 and CMS-10237]

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 October 26, 2018.

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 <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 Parham at (410) 786-1326.

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-10137 Solicitation for Applications for Medicare Prescription Drug Plan 2020 Contracts
CMS-10237 Medicare Advantage Application—Part C and 1876 Cost

Plan Expansion Application Regulations under 42 CFR 422 (Subpart K) & 417.400

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:* Solicitation for Applications for Medicare Prescription Drug Plan 2020 Contracts; *Use:* Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates, and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application.

Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and