

gsaadvantage.gov. The goal is to provide customer agencies with quality, meaningful, complete data to better search and compare products, thereby enhancing competition and saving taxpayer dollars. This endeavor is a critical piece of a larger effort to modernize the FSS program as a whole, under which FAS aims to increase efficiency and effectiveness, facilitate the purchase of total solutions, maximize competition, and promote small business utilization across Government.

The availability of MPN and UPC-A data improves overall data integrity, encouraging additional business from customers looking for the ability to quickly and accurately compare identical products. The standardization of part number data allows for greater transparency and improved business intelligence that will enable customers to make smarter, data-driven buying decisions. Collectively, these benefits will yield increased customer confidence as GSA works to make the FSS program the Government's premier acquisition vehicle.

Unaltered MPN data is required for all products, except where the manufacturer has not assigned a part number to identify the item. UPC-A data is required for all products for which this information is commercially available. The FAS performed market research to determine the Federal Supply Schedules and Special Item Numbers (SINs) under which UPC-A data is commercially available—a complete listing can be viewed at <http://eoffer.gsa.gov>.

MPN and UPC-A data is widely utilized throughout the commercial marketplace. FSS contractors are simply providing the existing MPN and UPC-A data that is used to classify their awarded FSS products. Many FSS contractors have already provided this data in their price lists. In fact, approximately 8 million MPNs and 1.3 million unique UPC-A codes are currently listed in FSS contractor price lists published on *gsaadvantage.gov*.

Obtaining MPN and UPC-A data from existing FSS contractors will allow GSA to acquire baseline information across the contracts already awarded under the FSS program. A bilateral “mass modification” will be distributed by GSA to all contractors with FSS contracts that include products. FSS contractors will be required to sign the modification and provide this data in their price lists within 60 days of distribution.

FSS contractors that do not provide this data will have noncompliant products “grayed-out” (*i.e.*, no longer

accessible/visible) within GSA's customer-facing eTools (GSA Advantage!, eBuy, etc.). In addition, GSA may consider noncompliance when determining whether to exercise the next contract option period. GSA might choose not to exercise the next option period, thereby allowing the contract to expire.

Dated: May 7, 2015.

Lisa P. Grant,

Deputy Assistant Commissioner, Office of Acquisition Management, Federal Acquisition Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-15AEZ; Docket No. CDC-2015-0028]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the proposed information collection entitled *Identification of Behavioral and Clinical Predictors of Early HIV Infection* (Project DETECT).

DATES: Written comments must be received on or before July 13, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0028 by any of the following methods:

- **Federal eRulemaking Portal:** *Regulation.gov*. Follow the instructions for submitting comments.
- **Mail:** Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any

personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: omb@cdc.gov.

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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited 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) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and

maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Identification of Behavioral and Clinical Predictors of Early HIV Infection (Project DETECT)—New—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 (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of HIV/AIDS Prevention (DHAP) requests a 3-year approval for a new data collection called “Identification of Behavioral and Clinical Predictors of Early HIV Infection (Project DETECT).”

CDC provides guidelines for HIV testing and diagnosis for the United States, as well as technical guidance for its grantees. CDC will use the HIV testing data collected for this project to update these guidance documents to reflect the latest available testing technologies, their performance characteristics, and considerations regarding their use. Specifically, CDC will describe the information on behavioral and clinical characteristics of persons with early infection to help HIV test providers (including CDC grantees) choose which HIV tests to use, and target tests appropriately to persons at different levels of risk. This information will be disseminated primarily through guidance documents and articles in peer-reviewed journals.

The primary study population will be persons at high risk for or diagnosed with HIV infection, many of whom will be men who have sex with men (MSM)

because the majority of new HIV infections occur each year among this population. The goals of the project are to: (1) characterize the performance of new HIV tests for detecting established and early HIV infection at the point of care, relative to each other and to currently used gold standard, non-POC tests, and (2) identify behavioral and clinical predictors of early HIV infection.

Project DETECT will enroll 1,667 persons annually at the primary study site clinic in Seattle, and an additional 200 persons will be enrolled from other clinics in the greater Seattle area. The study will be conducted in two phases.

Phase 1: After a clinic client consents to participate, he/she will be assigned a unique participant ID and will then undergo testing with the seven new HIV tests under study. While awaiting test results, participants will undergo additional specimen collections and complete the Phase 1 Enrollment Survey.

Phase 2: All Phase 1 participants whose results on the seven tests under investigation are not in agreement with one another (“discordant”) will be considered to have a potential early HIV infection. Nucleic amplification testing that detects viral nucleic acids will be conducted to confirm an HIV diagnosis and rule out false positives. Study investigators expect that each year, 50 participants with discordant test results will be invited to participate in serial follow-up specimen collections to assess the time point at which all HIV test results resolve and become concordant positive (indicating enrollment during early infection) or concordant negative (indicating one or more false-positive test results in Phase 1).

The follow-up schedule will consist of up to nine visits scheduled at regular intervals over a 70-day period. At each follow-up visit, participants will be tested with the new HIV tests and additional oral fluid and blood specimens will also be collected for

storage and use in future HIV test evaluations at CDC. Participants will be followed up only to the point at which all their test results become concordant. At each time point, participants will be asked to complete the Phase 2 HIV Symptom and Care survey that collects information on symptoms associated with early HIV infection as well as access to HIV care and treatment since the last Phase 2 visit. When all tests become concordant (*i.e.*, at the last Phase 2 visit) participants will complete the Phase 2 behavioral survey to identify any behavioral changes during follow-up. Of the 50 Phase 2 participants; it is estimated that no more than 26, annually, will have early HIV infection.

All data for the proposed information collection will be collected via an electronic Computer Assisted Self-Interview (CASI) survey. Participants will complete the surveys on an encrypted computer, with the exception of the Phase 2 Symptom and Care survey, which will be administered by a research assistant and then electronically entered into the CASI system. Data to be collected via CASI include questions on socio-demographics, medical care, HIV testing, pre-exposure prophylaxis, antiretroviral treatment, sexually transmitted diseases (STD) history, symptoms of early HIV infection, substance use and sexual behavior.

Data from the surveys will be merged with HIV test results and relevant clinical data using the unique identification (ID) number. Data will be stored on a secure server managed by the University of Washington Department of Medicine Information Technology (IT) Services.

The participation of respondents is voluntary. There is no cost to the respondents other than their time. The total estimated annual burden hours for the proposed project are 2,111 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Avg. burden per response (in hours) | Total burden hours |
|----------------------------------|--------------------------------------|-----------------------|------------------------------------|-------------------------------------|--------------------|
| Persons eligible for study | Phase 1 Consent | 2,334 | 1 | 15/60 | 584 |
| Enrolled participants | Phase 1 Enrollment Survey A | 1,667 | 1 | 45/60 | 1,251 |
| Enrolled participants | Phase 1 Enrollment Survey B | 200 | 1 | 1 | 200 |
| Enrolled participants | Phase 2 Consent | 50 | 1 | 15/60 | 13 |
| Enrolled participants | Phase 2 HIV Symptom and Care Survey. | 50 | 9 | 5/60 | 38 |
| Enrolled participants | Phase 2 Behavioral Survey | 50 | 1 | 30/60 | 25 |
| Total | | | | | 2,111 |

Leroy A. Richardson,
*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 Disease Control and
 Prevention**

[30Day-15-15JX]

**Agency Forms Undergoing Paperwork
 Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (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*. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

HIV Outpatient Study (HOPS)—New—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 nine 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 nine 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 9 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 | Avg. burden per response (in hrs.) |
|---------------------------|-------------------------|-----------------------|------------------------------------|------------------------------------|
| HOPS study Patients | Behavioral survey | 2,500 | 1 | 7/60 |
| HOPS Study Patients | Consent form | 450 | 1 | 15/60 |