

Estimated Total Annual Burden Hours: 630.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address:* infocollection@acf.hhs.gov.

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget,
Paperwork Reduction Project, *Fax:* 202-395-7285, *E-mail:* OIRA_SUBMISSION@OMB.EOP.GOV,
Attn: Desk Officer for the Administration for Children and Families.

Dated: November 10, 2010.

Robert Sargis,

Reports Clearance Officer.

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BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Development of Health Risk Assessment Guidance

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

ACTION: Request for Information.

SUMMARY: The Centers for Disease Control and Prevention (CDC) located within the Department of Health and Human Services (HHS) is seeking public comment on the development of guidance concerning Health Risk Assessment (HRAs). Section 4103 of the Affordable Care Act (ACA) (Pub. L. 111-148) requires that a health risk assessment be included in the annual wellness visit benefit authorized for Medicare beneficiaries under the ACA. CDC is collaborating with the Centers for Medicare and Medicaid Services (CMS), also located within HHS, in the

development of guidance for this type of assessment. This guidance is also intended to be useful for HRAs conducted in other patient populations such as privately insured populations, including those persons covered by employer healthcare plans. Comments received from this request for information will be used to inform the HRA guidance development process.

DATES: Written comments must be received on or before January 3, 2011. Comments received after January 3, 2011 will be considered to the extent possible.

ADDRESSES: You may submit written comments to the following address: Office of Prevention through Healthcare, Office of the Associate Director for Policy, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop D-28, Atlanta, Georgia, 30333, *ATTN:* Health Risk Assessment Guidance.

You may also submit written comments via e-mail to: OPTH@cdc.gov. Please use "Health Risk Assessment Guidance" for the subject line.

Submitted comments will be available for public review from Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m. Eastern Standard Time, at 1600 Clifton Road NE., Atlanta, Georgia 30333. Please call ahead to 1-404-639-0210 and ask for a representative in the Office of Prevention through Healthcare to schedule your visit. Comments will also be available for viewing at the following Internet address: <http://www.cdc.gov/policy/opth/>.

CDC will make all comments it receives available to the public without change, including personal information you may provide, which includes the name of the person submitting the comment or signing the comment on behalf of an organization, business, or any such entity. If anyone does not wish to have this information published, then that information should not be included when submitting the comment.

FOR FURTHER INFORMATION CONTACT:

Paula Staley, Office of Prevention through Healthcare, Associate Director for Policy, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop D-28, Atlanta, Georgia, 30333, telephone: (404) 639-0210.

SUPPLEMENTARY INFORMATION:

Section 4103 of the Affordable Care Act (ACA) requires that a health risk assessment be included in the annual wellness visit benefit authorized for Medicare beneficiaries under the ACA. CDC is collaborating with CMS to develop guidance for this type of assessment. This guidance is also

intended to be useful for HRAs conducted in other patient populations such as privately insured populations, including those persons covered by employer healthcare plans.

Currently there is considerable variation in available HRAs, with the majority of assessments created to support employer-based health and wellness programs. Several instruments have been created for use in research and are not available in the marketplace; and the scientific rigor of HRA tools is not always evident. Therefore, the development of HRA guidance is essential for effective implementation of this part of the Medicare wellness visit and to support broader HRA use within primary care.

Although comments on any aspect of the guidance development process will be accepted, comments are especially solicited about these areas of emphasis:

Content and Design

- Risk assessment domains—What are generic elements of any HRA and what elements must be tailored to specific populations, particularly those stratified by age?
- How should literacy and other cultural appropriateness factors be factored into the design?
- How should the HRA instrument support shared decision-making by provider and patient?

Mode of Administration

- How will individuals access the HRA (e.g., via kiosk or some other means in the physician's office, Internet, mail-in paper form, other non-traditional healthcare locations, such as, kiosk in a pharmacy)?
- What are the cultural appropriateness factors in patient HRA access?

Primary Care Office Capacity

- What primary care office capacity (personnel, Information Technology (IT), etc) is required to utilize HRA data effectively in support of personalized prevention planning?
- Are training and technical assistance necessary for effective practice utilization of an HRA? What entity should provide this technical assistance?
- What are potential or demonstrated community care transition linkages—follow-up outside the office by other providers—that help patients and providers manage priority risks identified by the HRA?
- What is the current practice of HRA in medical practices of various sizes, particularly those with five or fewer physicians?

Consumer/Patient Perspective

- How could HRA data be shared with the patients for their feedback and follow up in the primary care practice?
- What role, if any, do incentives play in motivating patients to take the HRA and/or participate in follow-up interventions?

Data

- With respect to Information Technology (IT), how could HRA data entered in any form populate electronic health records, and what special challenges and solutions occur if the data are entered in a non-electronic form?
- Are there standardized and certified tools available to support this data migration from multiple data entry sources?

Certification

- What certification tools and processes should complement the HRA guidance and how should they be made available to support primary care office selection of an HRA instrument?

Evaluation and Quality Assurance

- How should the HRA guidance be evaluated and updated with respect to individual and population-level (practice-based panel management) health outcomes?

Public Forum: CDC plans to convene a public forum in early February 2011 to highlight some of the key challenges, barriers, opportunities and innovations related to HRA standardization. The public forum will consist of panel presentations followed by public comment. CDC will publish a separate notice in the **Federal Register** announcing additional information for the Public Forum.

Dated: November 8, 2010.

Tanja Popovic,

*Deputy Associate Director for Science,
Centers for Disease Control and Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health**Government-Owned Inventions; Availability for Licensing**

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for

licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Novel Anti-HIV Acylthiol Drugs and Thioether Prodrugs

Description of Invention: The inventions provide the compositions, pharmaceutical carrier, and usages of the new Acylthiols (E-329-2000 family) and Thioether pro-drug (E-177-2010 family) compounds in treatment of retroviral infections such as HIV. More specifically, these compounds target the highly-conserved nucleocapsid protein of HIV-1. Activity of these compounds against the nucleocapsid protein leads to inactivation of the virus via disruption of the zinc fingers, integral for infectivity, without significantly affecting cellular proteins. Finally, these inventions can be prepared from inexpensive starting materials and two "one-pot" reactions. Thus, they open the possibility for an effective drug treatment for HIV that could reach underdeveloped countries. These new compounds have the potential to be used both as a systemic drug for the treatment of HIV-1 infection and as a topically-applied barrier to prevent viral transmission.

Applications: Treatment and prevention of HIV infections.

Advantages:

- Potent anti-HIV activity.
- Could be used both systemically and locally.
- Unlikely to develop any drug resistance.
- Can be inexpensively manufactured in a large scale.

Development Status: *In vitro* data available.

Market: According to the 2008 UNAIDS report, there were 33 million people living with AIDS in 2007, with 2.7 million new cases occurring in that year. In the US alone, there are 1.2 million AIDS patients.

The anti-HIV drug market is among the fastest-growing pharmaceutical markets in the world. Due to the large target market, duration of therapy (lifetime), and nature of the disease (incurable), manufacturers will continue to benefit from technological advancements. In 2007, the seven Major Markets (7MM; US, Japan, Italy, Germany, UK, Spain and France) generated \$9.3B in sales of antiretroviral drugs. These markets are expected to grow to \$15.1B by 2017.

The current product market segments for anti-retrovirals are: protease inhibitors (PI), nucleoside reverse transcriptase inhibitors (NRTI), non-nucleoside reverse transcriptase inhibitors (NNRTI), entry inhibitors (EI), integrase inhibitors (II), and maturation inhibitors (Other).

Inventors: Daniel Appella (NIDDK), Ettore Appella (NCI), John K. Inman (NIAID), Deyun Wang (NIDDK), Lisa M. Miller Jenkins (NCI), Ryo Hayashi (NCI).

Publications:

1. Miller Jenkins LM, *et al.* Nature Chemical Biology, in press.
2. Miller Jenkins LM, *et al.* Specificity of acyl transfer from 2-mercaptobenzamide thioesters to the HIV-1 nucleocapsid protein. J Am Chem Soc. 2007 Sep12;129(36):11067-11078. [PubMed: 17705474]
3. Schito ML, *et al.* In vivo antiviral activity of novel human immunodeficiency virus type 1 nucleocapsid p7 zinc finger inhibitors in a transgenic murine model. AIDS Res Hum Retroviruses. 2003 Feb;19:91-101. [PubMed: 12639244]

Patent Status:

- U.S. Provisional Application No. 61/353,274 filed 10 Jun 2010 (HHS Reference No. E-177-2010/0-US-01).
- PCT/US02/23924 (HHS Reference No. E-329-2000/0-PCT-02) and entered national stage in the U.S. (Patent No. 7,528,274 and Patent Application No. 12/414,321), Canada (Patent Application No. 2456083), Australia (Patent No. 2002322721), and Europe (Patent Application No. 02756732.0).

Licensing Status: Available for licensing.

Licensing Contact: Sally Hu, Ph.D.; 301-435-5606; Hus@mail.nih.gov.

Collaborative Research Opportunity: The Laboratory of Cell Biology, Center for Cancer Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the above invention for the treatment/prevention of HIV infection. Please contact John Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.