

fnic.nal.usda.gov/dietary-guidance/dietary-reference-intakes/dri-reports.

It has become apparent that a number of unanticipated challenges were encountered when chronic disease endpoints were considered as indicators for setting DRI reference values. Many of these challenges were discussed in a 2007 “lessons learned” workshop conducted by the IOM after the first six DRI reports were published.³ Other scientific publications have also discussed the challenges, but approaches for addressing the identified challenges have not yet been adequately explored.

Recently, the DRI Committees of the U.S. and Canadian governments called for nominations for nutrients to be considered for future DRI reviews. Many of the nominated nutrients cited new data on chronic disease relationships as the justification for new DRI reviews, including three of the four nutrients selected by the DRI Committees for further consideration based on the availability of sufficient new and relevant evidence. Given the clear need for more in-depth evaluation of the challenges involved in incorporating chronic disease endpoints into DRI processes prior to initiating a new DRI review, the two government committees announced plans to sponsor a workshop to be held in 2015 to address whether, and how, chronic disease outcomes can be incorporated into the process of setting DRI values.

The limited time available for the workshop may preclude consideration of all issues relevant to the incorporation of chronic disease endpoints into DRI processes. As warranted, subsequent activities will address issues that arise in the workshop or that have been identified in other activities but not covered in workshop discussions.

Written Public Comments

The key questions for the workshop, on which the committees would like public comments, are derived from prior discussions of the major challenges in incorporating chronic disease endpoints into DRI considerations:

1. What dose-response models can be considered for future DRI reviews when chronic disease endpoints are used?
 - a. What are the scientific issues?
 - b. What are the options for addressing these issues?

c. What are the advantages and disadvantages of the various options?

2. What are the evidentiary challenges important in selecting and using chronic disease endpoints in future DRI reviews?

- a. What are the scientific issues?
- b. What are the options for addressing these issues?

c. What are the advantages and disadvantages of the various options?

3. What arguments can be made for and against continuing to include chronic disease endpoints in future DRI reviews?

- a. What are the scientific issues?
- b. What are the options for addressing these issues?
- c. What are the advantages and disadvantages of the various options?

Public comments are to be submitted via email to DRI@hhs.gov. Provide a brief summary (approx. 250 words) of the points or issues. If providing literature or other resources, one of the following forms is preferred:

- Complete citation, as in a bibliographic entry
- Abstract
- Electronic link to full article or report

Please provide comments as early as possible in order to increase the likelihood of having a meaningful impact, as the workshop panelists will be considering them prior to the workshop. The deadline for comment submission is Friday, January 30, 2015. Comments received later than January 30, 2015 will not be considered.

Meeting Registration: The meeting will be publicly accessible both in-person and by videocast on the Internet. Due to limited seating capacity, registration will be required for in-person attendance. Notice of registration will be available on <http://www.health.gov/dri> prior to the workshop; registration is expected to open on or about February 15, 2015.

Dated: December 16, 2014.

Don Wright,

Deputy Assistant Secretary for Health,
Office of Disease Prevention and Health Promotion,
Office of the Assistant Secretary for Health,
U.S. Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-15-14AQA]

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

The Enhanced STD Surveillance Network (eSSuN)—NEW—Division of STD Prevention (DSTDP), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

³ The Development of DRIs 1994–2004: Lessons Learned and New Challenges, Workshop Summary, November 30, 2007. Available from: <http://www.iom.edu/Reports/2007/The-Development-of-DRIs-1994-2004-Lessons-Learned-and-New-Challenges-Workshop-Summary.aspx>.

Background and Brief Description

The Enhanced STD surveillance network Project is an active STD sentinel surveillance network comprised of 10 surveillance sites including Baltimore City Health Department, California Department of Public Health, Florida Department of Health, Massachusetts Department of Public Health, Minnesota Department of Health, Multnomah County Health Department, New York City Department of Health & Mental Hygiene, Philadelphia Department of Public Health, San Francisco Department of Public Health, and Washington State Department of Health.

The purpose of eSSuN is to be a robust platform for the identification of STD trends, monitor STD epidemiology and evaluate the effectiveness of public health interventions through active surveillance collection, reporting, analysis, visualization (e.g., mapping) and interpretation of disease information.

The objectives of the eSSuN project are (1) provide a dataset of supplemental information on gonorrhea case reports of STDs of interest; (2) provide geographic information on case reports of STDs of interest for investigating social determinants of STDs; (3) monitor screening coverage for chlamydial infection among young women in sentinel clinical settings; (4) monitor STD screening, incidence, prevalence, epidemiologic and health care access trends in populations of interest such as men-who-have-sex-with men (MSM), young people and persons diagnosed with gonorrhea; (5) monitor STD treatment and prevention service practices; (6) monitor selected adverse health outcomes of STDs; (7) evaluate and enhance local and state STD surveillance capacity; (8) enhance local STD-specific health information technology and epidemiologic capacity, and, (9) establish a core of exemplary state, tribal, territorial, county and/or city health department STD surveillance approaches to STD surveillance.

This project will utilize two distinct surveillance strategies to collect information. The first strategy employs facility-based sentinel surveillance, which will abstract standardized data from existing electronic medical records for all patient visits to participating STD clinics and female patients aged 15–44 years of age visiting participating family

planning/reproductive health clinics and other facilities (school-based clinics and federally qualified healthcare centers) during the project period. The second strategy is population-based STD surveillance among a random sample of reported gonorrhea cases. Sampled cases will be contacted for standardized interview and the sample fraction will be 250 completed enhanced investigations or up to 2.5% of total morbidity if annual cases exceed 10,000 cases. Enhanced investigations will also include verification of treatment and an internal health department record review (performed on either all cases or on the sampled cases).

For the facility-based component of eSSuN, participating sites have developed common protocols stipulating data elements to be collected, including patient demographics, clinical, risk and sexual behaviors. The specified data elements are abstracted by clinic staff from existing electronic medical records for: (1) all patient visits to participating STD clinics, (2) female patients aged 15–24 at participating family planning/reproductive health clinics and, (3) visits of female patients aged 15–44 at school-based clinics and those attending federally qualified health centers (FQHCs) specifically for family planning services.

Some of the participating facilities are satellites clinics of large network providers where clinical data systems are centralized. Hence, there are a total of 22 unique clinic data managers that will be abstracting the facility data. Each of the 22 clinic data managers will spend 3 hours to extract and transmit data to local/state health departments. Individual patient records are de-identified (all patient-specific identifiers are removed) by clinic staff before being transmitted to health departments, who recode the data into standardized formats before being transmitted to CDC through secure file transport mechanisms. Data transmission will occur on a monthly basis. Each eSSuN site will spend 16 hours to recode and transmit the data to CDC every month. At CDC, data will be aggregated across all participating sites in a common data structures and formatted for analysis.

For the population-based surveillance component, a random sample of individuals residing within participating jurisdictions and reported

with gonorrhea will be interviewed using locally designed interview templates following standardized data protocols. Enhanced data collection includes detailed information on demographic characteristics, behavioral risk factors and clinical history of persons with gonorrhea. Each of the 10 sites will interview a minimum of 250 persons (or up to 2.5% of total morbidity if annual GC cases exceed 10,000 cases) and each interview is expected to take 10 minutes per person. Interview data for the population-based component will be collected through telephone administered or in-person interviews conducted by trained interviewers in the 10 eSSuN sites. These data will be directly entered into existing STD surveillance information systems at each health department. Data will be locally extracted, de-identified and recoded into standardized formats prior to being transmitted to CDC through secure file transport mechanisms on a monthly basis.

Patient participation in the interview is voluntary and refusal to participate has no impact on other STD services the local health provides to persons diagnosed with gonorrhea. There is no cost to the respondents beyond their time and no compensation for participation.

Both components of eSSuN are designed to (1) integrate traditional surveillance methods with innovative data management technologies to produce high-quality, timely surveillance and epidemiologic data, (2) provide valuable information to direct public health STD prevention and control efforts, (3) enhance understanding of the community burden of disease, (4) identify syndemic patterns and population at greatest risk, and, (5) monitor long-term health consequences of STDs. The eSSuN surveillance platform allows CDC to establish and maintain common standards for data collection, transmission, and analysis, and to build and maintain STD surveillance expertise in 10 state or city health departments. Such common systems, established mechanisms of communication, and in-place expertise are all critical components for timely, flexible, and high quality surveillance.

The total estimated annual burden is 2,854 hours of effort.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Average burden per response (hours) |
|--|--|-----------------------|------------------------------------|-------------------------------------|
| Clinic Data manager at clinic | Data Manager electronic Transmission | 22 | 6 | 3 |
| Health Department Data Manager | Record Abstraction (No Form) | 10 | 12 | 16 |
| Gonorrhea Patients sampled and interviewed | Case Reports (No Form) | 3,225 | 1 | 10/60 |
| | Patient Interview | | | |

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 Medicare & Medicaid Services

[Document Identifiers: CMS-10536 and
CMS-R-262]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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 any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) 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 *January 20, 2015*.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 *OR* Email: *OIRA_submission@omb.eop.gov*.

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' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
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: Reports Clearance Office at (410) 786-1326.

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:* Medicaid Eligibility and Enrollment (EE) Implementation Advanced Planning Document (IAPD) Template; *Use:* To assess the appropriateness of states' requests for enhanced federal financial participation for expenditures related to Medicaid eligibility determination systems, we will review the submitted information and documentation to make an approval determination for the advanced planning document. The package has been revised subsequent to the publication of the 60-day **Federal Register** notice (79 FR 51571). *Form Number:* CMS-10536 (OMB control number: 0938-New); *Frequency:* Yearly, once, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 168; *Total Annual Hours:* 1,344. (For policy questions regarding this collection contact Christine Gerhardt at 410-786-0693).

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* CY 2016 Plan Benefit Package (PBP) Software and Formulary Submission; *Use:* We require that Medicare Advantage and Prescription Drug Plan organizations submit a completed PBP and formulary as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to us for review and approval. We publish beneficiary education information using a variety of formats. The specific education initiatives that utilize PBP and formulary data include web application tools on www.medicare.gov and the plan benefit insert in the Medicare & You handbook. In addition, organizations utilize the PBP data to generate their Summary of Benefits marketing information. Please note that the package has been revised subsequent to the publication of the 60-day **Federal Register** notice (79 FR 57931). *Form Number:* CMS-R-262 (OMB control