DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2011–0011]

Public Health Service Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Solid Organ Transplantation

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

ACTION: Notice of availability and request for public comment.

SUMMARY: With this notice, the Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) requests public comment on the draft Public Health Service Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) through Solid Organ Transplantation (Draft Guideline). The Draft Guideline can be found at http://www.regulations.gov under Docket No. CDC–2011–0011.

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project


Background and Brief Description

The CDC is requesting OMB approval for three additional years to use this generic clearance for a research program focused on identifying the environmental causes of foodborne illness. This revision will provide OMB clearance for EHS–Net data collections conducted in 2011 through 2014 (a maximum of 3 annually). The program is revising the generic information collection request (ICR) to reduce the number of respondent groups, reduce the number of studies conducted and the estimated burden, and collect more generalizable data.

Reducing foodborne illness first requires identification and understanding of the environmental factors that cause these illnesses. We need to know how and why food becomes contaminated with foodborne illness pathogens. This information can then be used to determine effective food safety prevention methods. The purpose of this food safety research program is to identify and understand environmental factors associated with foodborne illness and outbreaks. This program will continue to involve up to 3 data collections a year. This program is conducted by the Environmental Health Specialists Network (EHS–Net), a collaborative project of CDC, FDA, USDA, and six state/local sites (CA, NYC, NY, MN, RI, and TN).

Environmental factors associated with foodborne illness include both food safety practices (e.g., inadequate cleaning practices) and the factors in the environment associated with those practices (e.g., worker and retail food establishment characteristics). To understand these factors, we need to continue to collect data from those who prepare food (i.e., food workers) and on the environments in which the food is prepared (i.e., retail food establishment kitchens). Thus, our respondents will be retail food establishment food workers.

For each data collection, we will collect data in approximately 480 retail food establishments. For each data collection, we will collect data from a maximum of 1,440 workers. Each respondent will respond only once and the average burden per response will be approximately 30 minutes. We will conduct up to 3 data collections a year. The maximum annual interview/survey burden for all 3 data collections will be 2,160 hours.

We expect a worker response rate of approximately 70 percent. Thus, for each data collection, we will need to conduct a recruiting screener with approximately 2,057 worker respondents to obtain the needed number of respondents. Each respondent will respond only once and the average burden per response will be 3 minutes. As we plan to conduct up to 3 data collections annually, the maximum annual recruiting screener burden will be 309 hours. The total maximum annual burden will be 2,469 hours. There is no cost to the respondents other than their time.

## Estimated Annualized Burden Hours

<table>
<thead>
<tr>
<th>Type of respondents</th>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response (in hours)</th>
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<tbody>
<tr>
<td>Retail food workers</td>
<td>Interview/survey</td>
<td>4,320</td>
<td>1</td>
<td>30/60</td>
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<tr>
<td>Retail food workers</td>
<td>Recruiting screener</td>
<td>6,171</td>
<td>1</td>
<td>3/60</td>
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</table>

Dated: September 13, 2011.

Daniel Holcomb,
Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–24187 Filed 9–20–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2011–0011]

Public Health Service Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Solid Organ Transplantation

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).
Also found at the docket is a supporting document for reference, the Evidence Report. The Evidence Report includes primary evidence, studies, and data tables that were used by the Guideline authors in developing the recommendations in the Guideline.

The Draft Guideline is for use by organ procurement organizations (OPOs); transplant centers, including physicians, nurses, administrators, and clinical coordinators; laboratory personnel responsible for testing and storing donor and recipient specimens; and persons responsible for developing, implementing, and evaluating infection prevention and control programs for OPOs and transplant centers. This Draft Guideline provides evidence-based recommendations for reducing unexpected transmission of HIV, HBV and HCV from deceased and living organ donors.

DATES: Written comments must be received on or before November 21, 2011.

ADDRESSES: Written comments may be submitted electronically or by mail. You may also submit written comments electronically to: http://www.regulations.gov. Comments must be identified by Docket No. CDC–2011–0011. Please follow directions at http://www.regulations.gov to submit comments.

You may also submit written comments to the following address: Office of Blood, Organ, and Other Tissue Safety, Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, Attn: Public Health Service Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) through Solid Organ Transplantation, Docket No. CDC–2011–0011, 1600 Clifton Road NE., Mailstop A–07, Atlanta, Georgia, 30329. All written materials identified by Docket No. CDC–2011–0011 will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., Eastern Daylight Time, at 1600 Clifton Road, NE., Atlanta, Georgia 30333.

Please call ahead to (404) 639–4000 and ask for a representative from the Office of Blood, Organ and Other Tissue Safety to schedule your visit. All public comments will be reviewed and considered prior to finalizing the Draft Guideline. All relevant comments received will be posted publicly without change, including any personal or proprietary information provided. To download an electronic version of the Draft Guideline, access http://www.regulations.gov. Docket No. CDC–2011–0011.

FOR FURTHER INFORMATION CONTACT: Debbie Seem, Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop A–07, Atlanta, Georgia, 30329–4018; Telephone: (404) 639–4000.

SUPPLEMENTARY INFORMATION: Since 2008, CDC has collaborated with state and federal agencies, national partners, academicians, public and private health professionals, the transplant field, public health organizations, and other partners to revise and expand the 1994 Guidelines for Preventing Transmission of Human Immunodeficiency Virus (HIV) through Transplantation of Human Tissue and Organs (1994 Guideline). The 2011 Draft Guideline updates the previous recommendations for HIV, includes recommendations to reduce disease transmission of HBV and HCV, and addresses issues such as donor risk assessment, donor screening, HBV- and HCV-infected donors and transplantation, recipient informed consent, recipient screening, donor and recipient specimen collection and storage, and tracking and reporting of HIV, HBV, and HCV. As with the 1994 Guideline, the recommendations address adult and pediatric donors who are living or deceased, as well as transplant candidates and recipients. In addition to summarizing current scientific knowledge about solid organ transplant safety, the 2011 Draft Guideline also identifies important gaps in the literature where further research is needed.

CDC worked with the University of Pennsylvania’s Health System Center for Evidence-based Practice (CEP) and sought input in each phase of the Draft Guideline’s development from subject matter experts in HIV and hepatitis through formation of a Guideline Expert Panel to develop the new Draft Guideline. CDC also formed a Guideline Review Committee to provide feedback on the Draft Guideline recommendations. Members of the Review Committee included representatives from public health, the regulatory arena, transplant infectious disease experts, and other stakeholders. This new Draft Guideline will not be a federal rule or regulation.

Dated: September 13, 2011.

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

[FR Doc. 2011–24189 Filed 9–20–11; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Temporary Assistance for Needy Families/National Directory of New Hires Match Results Report.

OMB No.: 0970–0311.

Description: Section 453(j)(3) of the Social Security Act (the Act) allows for matching between the National Directory of New Hires (maintained by the Federal Office of Child Support Enforcement (OCSE)) and State TANF Agencies for purposes of carrying out responsibilities under programs funded under part A of Title IV of the Act. To assist OCSE and Office of Family Assistance (OFAP) in measuring savings to the TANF program attributable to the use of NDNH data matches, the State TANF Agencies have agreed to provide OCSE with a written description of the performance outputs and outcomes attributable to the State TANF Agency’s use of NDNH match results. This information will help OCSE demonstrate how the NDNH supports the OCSE’s mission and strategic goals.

Respondents: State TANF Agencies.

Annual Burden Estimates

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours *</th>
</tr>
</thead>
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<tr>
<td>TANF/NDNH Match Results Report</td>
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