

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), announces the availability of the following publication: *National Occupational Research Agenda (NORA) National Total Worker Health® Agenda (2016–2026): A National Agenda to Advance Total Worker Health® Research, Practice, Policy, and Capacity* [2016–114].

ADDRESSES: This document may be obtained at the following link <http://www.cdc.gov/niosh/docs/2016-114/>.

FOR FURTHER INFORMATION CONTACT: Sara L. Tamers, Ph.D., MPH, NIOSH/CDC, Telephone: (202) 245–0677, Fax: (202) 245–0664 (not toll-free numbers), email: STamers@cdc.gov.

Dated: April 22, 2016.

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

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Child Support Noncustodial Parent Employment Demonstration (CSPED).

OMB No.: 0970–439.

Description: The Office of Child Support Enforcement (OCSE) within the Administration for Children and Families (ACF) seeks an extension without change for an existing data collection called the Child Support Noncustodial Parent Employment Demonstration (CSPED) through September 30, 2018 (OMB no. 0970–439; expiration date September 30, 2016). OCSE is proposing that this information collection be extended to continue using 8 of the 10 currently approved information collection instruments with a reduction in burden hours to reflect only the extension period, estimated to be two years and three months, from July 1, 2016 to September 30, 2018.

In October 2012, OCSE issued grants to eight state child support agencies to provide employment, parenting, and child support services to noncustodial parents who are having difficulty meeting their child support obligation. The overall objective of the CSPED

evaluation is to document and evaluate the effectiveness of the approaches taken by these eight CSPED grantees. This evaluation will yield information about effective strategies for improving child support payments by providing noncustodial parents employment and other services through child support programs. It will generate extensive information on how these programs operated, what they cost, the effects the programs had, and whether the benefits of the programs exceed their costs. The information gathered will be critical to informing decisions related to future investments in child support-led employment-focused programs for noncustodial parents who have difficulty meeting their child support obligations.

The CSPED evaluation includes the following two interconnected components or “studies”:

1. **Implementation and Cost Study.** The goal of the implementation and cost study is to provide a detailed description of the programs—how they are implemented, their participants, the contexts in which they are operated, their promising practices, and their costs. The detailed descriptions will assist in interpreting program impacts, identifying program features and conditions necessary for effective program replication or improvement, and carefully documenting the costs of delivering these services. Key activities of the implementation and cost study include: (1) Conducting semi-structured interviews with program staff and selected community partner organizations to gather information on program implementation and costs; (2) conducting focus groups with program participants to elicit participation experiences; (3) administering a web-based survey to program staff and community partners to capture broader staff program experiences; and (4) collecting data on study participant service use, dosage, and duration of enrollment throughout the demonstration using a web-based Management Information System (MIS).

2. **Impact Study.** The goal of the impact study is to provide rigorous estimates of the effectiveness of the eight programs using an experimental research design. Program applicants who are eligible for CSPED services are randomly assigned to either a program group that is offered program services or a control group that is not. The study MIS that documents service use for the implementation study is also used by grantee staff to conduct random assignment for the impact study. The impact study relies on data from surveys of participants, as well as administrative

records from state and county data systems. Survey data are collected twice from program applicants. Baseline information is collected from all noncustodial parents who apply for the program prior to random assignment. A follow-up survey is collected from sample members twelve months after random assignment. A wide range of measures are collected through surveys, including measures of employment stability and quality, barriers to employment, parenting and co-parenting, and demographic and socio-economic characteristics. In addition, data on child support obligations and payments, Temporary Assistance for Needy Families (TANF) and Supplemental Nutrition Assistance Program (SNAP) benefits, Medicaid receipt, involvement with the criminal justice system, and earnings and benefit data collected through the Unemployment Insurance (UI) system are obtained from state and county databases.

Two components of the data collection have been completed: (1) Focus groups with program participants; and (2) the web-based survey to document program staff and partner experiences. The following data collection activities are not yet complete: (1) The staff interview topic guide; (2) the study MIS functions for tracking participation in the program; (3) the introductory script which program staff use to introduce the study to participants; (4) the introductory script heard by program applicants; (5) the baseline survey; (6) the study MIS functions for conducting random assignment; (7) the protocol for collecting child support, benefit, earnings, and criminal justice data from state and county administrative data systems; and (8) the 12-month follow-up survey. As of January 1, 2016, 8,060 participants have been enrolled and completed the baseline survey and over 2,300 participants have completed the 12-month follow-up survey.

Respondents

Respondents to these activities include program applicants, study participants, grantee staff and community partners, as well as state and county staff responsible for extracting data from government databases for the evaluation. Specific respondents per instrument are noted in the burden tables below.

Annual Burden Estimates

The following instruments are proposed for public comment under this 60-Day **Federal Register** Notice. The following table provides the burden

estimates for the implementation and cost study and the impact study components of the current request. The

requested extension period is estimated to be two years and three months, from July 1, 2016 to September 30, 2018.

Thus, burden hours for all components are annualized over two years and three months.

IMPLEMENTATION AND COST STUDY

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Total annual burden hours ^a
Staff interview topic guide	120	1	1	120	53
Study MIS to track program participation	200	468.75	0.0333	3,125	1,390

Impact Study

Introductory script:					
Grantee staff	120	9	0.1667	180	80
Program applicants ^b	1,050	1	0.1667	175	78
Baseline survey	1,000	1	0.5833	583	259
Study MIS to conduct random assignment	120	9	0.1667	180	80
Protocol for collecting administrative records	32	1	8	256	114
12 month follow-up survey	1,476	1	0.75	1,107	492

^a All burden estimates are annualized over 2.25 years.

^b Five percent of program applicants are not expected to agree to participate in the study; thus there are 5% more program applicants than study participants.

Estimated Total Annual Burden Hours: 2,546.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) the quality, utility, and clarity of the information to be collected; and (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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,
Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-N-2016-1134]

Public Meeting on Patient-Focused Drug Development for Patients Who Have Received an Organ Transplant

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for patients who have received an organ transplant. Patient-Focused Drug Development is part of FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patient perspectives on the impact of receiving an organ transplant on daily life and patient views on treatment approaches; the input from this public meeting will help in developing topics for further discussion. FDA is also interested in discussing issues related to scientific challenges in developing drugs to manage organ transplantation. In the afternoon, FDA will hold a workshop and provide information for and gain perspective from patients and patient advocacy organizations, health care providers, academic experts, and industry on various aspects of clinical

development of drug products intended to manage organ transplantation.

DATES: The public meeting will be held on September 27, 2016, from 9 a.m. to 5 p.m. Please register here for the meeting by September 20, 2016: <http://organtransplantpfdd.eventbrite.com>. Submit electronic or written comments to the public docket by November 27, 2016.

ADDRESSES: The meeting and workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm.1503), Silver Spring, MD 20993-0002. Participants must enter through Building 1 and undergo security screening. For more information on parking and security procedures, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or