programmatic information on activities and objectives will continue to be collected twice per year.

The National Asthma Control Program at CDC has access to and analyzes national-level asthma surveillance data (*http://www.cdc.gov/asthma/asthmadata.htm*). With the exception of data from the Behavioral Risk Factor Surveillance System (BRFSS), state level analyses cannot be performed. Therefore, as part of AIRS, state asthma control programs submit aggregate surveillance data to allow calculation of asthma surveillance indicators across all funded states (where data are available) in a standardized manner. Data requests through this system regularly include: Hospital discharges (with asthma as first listed diagnosis), and emergency department visits (with asthma as first listed diagnosis). Under AIRS, participating states annually submit this information to the AIRS system in conjunction with an end-of-year report describing state activities that meet project objectives described above.

National and state asthma surveillance data provide information useful to examine progress on long-term outcomes of state asthma programs. To identify appropriate indicators of program implementation and short-term outcomes for AIRS, CDC previously convened and facilitated workgroups comprised of state asthma control program representatives to generated specific questions to collect data on key features of state asthma control programs: Partnerships, surveillance, interventions, and evaluation.

With technical assistance provided by NCEH staff, AIRS has provided states with uniform data reporting methods and linkages to other states' asthma programs and data. Thus, AIRS has saved state resources and staff time when they embark on asthma activities similar to those being done elsewhere. Also, the AIRS system has been similarly helpful in linking states together on occasions when a given state seeks to report their results at national meetings or publish their findings and program results in scholarly journals. For example, with CDC staff, three state programs co-presented on a panel regarding evaluations of their asthma partnerships at the November, 2012 American Evaluation Association's *Evaluation 2012* conference.

In addition, CDC staff have regularly made requests from AIRS to obtain standardized summaries of state programs regarding such activities as the number of states meeting staffing requirements, number and timeliness of state strategic evaluation plans, topics for individual evaluation selected by states, types and targets of interventions, and use of asthma surveillance data in state programs.

Furthermore, access to standardized AIRS surveillance and programmatic data allows CDC to provide timely and accurate responses to the public and Congress regarding the NCEH asthma program (e.g., how many states have asthma interventions targeting schools, how many children are treated in emergency departments, etc.).

There will be no cost for respondents, other than their time, to participate in AIRS. Based on the program's evaluation of past performance, it was noted that the hours for the interim report should be increased from 2 to 4 hours and those of the end of year be decreased from 6 to 4 hours; however, total burden hours remain at 8 hours per year per respondent. The total estimated annual burden hours are 288.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
State Health Departments	Interim report on activities and objectives	36	1	4
State Health Departments	End of year report on activities, objectives and aggregate surveillance.	36	1	4

Ron A. Otten,

Director, 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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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

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

OMB No.: 0970—NEW.

Description: The Office of Child Support Enforcement (OCSE) within the Administration for Children and Families (ACF) is proposing data collection activity as part of the Child Support Noncustodial Parent Employment Demonstration (CSPED). 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 will include 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 will 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 will be randomly assigned to either a program group that is offered program services or a control group that is not. The study MIS that will document service use for the implementation study will also be used by grantee staff to conduct random assignment for the impact study. The impact study will rely on data from surveys of participants, as well as administrative records from state and county data systems. Survey data will be collected twice from program applicants. Baseline information will be collected from all noncustodial parents who apply for the program prior to random assignment. A follow-up survey will be collected from sample members twelve months after random assignment. A wide range of measures will be 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 will be obtained from state and county databases.

A 60-Day **Federal Register** Notice was published for this study on January 11, 2013. This 30-Day **Federal Register** Notice covers the following data collection activities: (1) Topic guides for semi-structured interviews with program staff and community partners, (2) focus group guides for program participants, (3) the web-based survey to document program staff and partner experiences, (4) the Management Information System (MIS) functions for tracking participation in the program, (5) an introductory script which program staff will use to introduce the study to participants, (6) the baseline survey used to capture participant characteristics prior to randomization, (7) the MIS functions for conducting random assignment, and (8) the extraction of child support, benefit, earnings, and criminal justice data extracted from state and county administrative data systems.

Respondents: Respondents 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 table below.

Annual Burden Estimates

The following tables provide the burden estimates for the implementation and cost study and the impact study components of the current request.

IMPLEMENTATION AND COST STUDY

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Staff interview topic guide with program staff and community partners	120	2	1	240
Focus group guide with program participants	240	1	1.5	360
Web survey of program staff and community partners	200	2	0.5	200
Study MIS for grantee and partner staff to track program participation	200	1,500	0.0333	10,000

IMPACT STUDY

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Introductory script:				
Grantee staff	120	105	0.1667	2,100
Program applicants [1]	12,600	1	0.1667	2,100
Baseline survey of study participants	12,000	1	0.5833	7,000
Study MIS used by program staff to conduct random assignment	120	105	0.1667	2,100
Protocol for collecting administrative records	32	2	8	512

[1] 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: 8,204.

Additional Information: In compliance with the requirements of Section 3506(c)(2)(A) of the Paper Work 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 may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 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. Email 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, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–09797 Filed 4–24–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0642]

Assay Migration Studies for In Vitro Diagnostic Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Assay Migration Studies for In Vitro Diagnostic Devices.'' This guidance presents a least burdensome regulatory approach to gain FDA approval of Class III or certain licensed in vitro diagnostic devices in cases when a previously approved assay is migrating (i.e., transitioning) to a new system for which the assay has not been previously approved, licensed, or cleared.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Assay Migration Studies for In Vitro Diagnostic Devices'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. Alternatively, you may submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, suite 200N, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sally Hojvat, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5524, Silver Spring, MD 20993–002, 301–796–5455.

For further information concerning the study designs in the guidance:

Marina V. Kondratovich, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5666, Silver Spring, MD 20993–002, 301–796–6036.

For further information concerning the guidance as it relates to devices regulated by CBER:

Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry and FDA staff entitled ''Assay Migration Studies for In Vitro Diagnostic Devices.'' This guidance presents a least burdensome regulatory approach to gain FDA approval of Class III or certain licensed in vitro diagnostic devices in cases when a previously approved assay is migrating (i.e., transitioning) to a new system for which the assay has not been previously approved or licensed. The approach in this guidance is also applicable for some 510(k) cleared devices for which transition to a new system presents specific concerns, either because of the nature of the analyte and indications, or because of the specific technology used (e.g., nucleic acid amplification tests). The focus of this guidance is on the study designs and performance criteria that should be fulfilled in order for a sponsor to utilize the migration study approach in support of the change. The FDA believes that the assay migration study paradigm discussed in this guidance provides a least burdensome scientific and regulatory pathway for manufacturers to transfer a previously approved or licensed assay with full clinical data from an old system to a new system (previously not approved or licensed). The paradigm is suitable in cases when sufficient knowledge can be derived from the documentation of design controls, risk analyses, and prior performance studies on an old system.

The draft of this guidance was issued on January 5, 2009 (74 FR 302). The comment period closed on April 6, 2009. Three sets of comments were received and reviewed by FDA. The guidance was updated to address comments where appropriate. The updated guidance contains additional examples and explanations and supersedes the draft guidance ''Assay Migration Studies for In Vitro Diagnostic Devices'' issued on January 5, 2009.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on ''migration studies'' for in vitro diagnostic device. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To receive ''Assay Migration Studies for In Vitro Diagnostic Devices,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1660 to identify the guidance you are requesting. Guidance documents are also available on the CBER Internet site at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.*

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The