performance and status indicators, risk analysis and loss information, Basel II parameters and identifier variables (such as customer and co-borrower ID). Also, the Federal Reserve proposes to remove three data items from the loan level table that can be derived from other data items.

The Federal Reserve specifically requests comment on an institution's ability to report data related to Loss Given Default (LGD) on first Lien and home equity loans in cases of involuntary termination. The Federal Reserve specifically requests comment on what information, in addition to total debt at time of any involuntary termination, net recovery amount, and sales price of property, would be appropriate to collect in order to estimate LGD.

Domestic Home Equity Loan and Home Equity Line Schedule

The Federal Reserve proposes adding 27 data items to the Domestic Home Equity Loan and Home Equity Line schedule and deleting one data item. The Federal Reserve proposes adding the data items to provide more information on loan performance, including loss, default, modification, foreclosure and recovery variables, and Basel II parameters, and to be consistent with the proposed revisions to the Domestic First Lien Closed End 1–4 Family Residential Loan schedule, as discussed above. The Federal Reserve proposes to delete the Paid-in-Full Coding data item (Field 52), as this information is sufficiently captured in the Liquidation Status data item (Field 54).

Address Matching Loan Level Data Collection

The Federal Reserve proposes to add one data item to the Address Matching Loan Level Data Collection schedule to indicate whether the loan is included in the FR Y–14M First Lien Closed-End or Home Equity Loan and Home Equity Line schedule for that month.

Domestic Credit Card Data Collection Data Dictionary

The Federal Reserve proposes to add 65 data items to the Domestic Credit Card Data Collection Data Dictionary schedule. 46 data items would be added at the account level to collect information surrounding identifier variables (including corporation and borrower IDs, address, entity type, and trade key), purchase and payment rate variables, status and performance data, various fees incurred, workout program descriptors, and credit scores and limits. In addition, the Federal Reserve proposes to revise the current reporting of 11 account level data items from optional to mandatory, in order to create greater uniformity in the reporting of balance, cycle and account dates and amounts. At the portfolio level, 19 data items would be added to collect information on interest and non-interest expenses, interest and noninterest income, various types of fee income, and taxes.

Copies of the draft reporting forms and instructions and additional details on the proposed data items are available on the Federal Reserve Board's public Web site at: *http://www.federalreserve.gov/apps/reportforms/review.aspx.*

Board of Governors of the Federal Reserve System, December 14, 2012.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2012–30636 Filed 12–19–12; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Health Profession Opportunity Grants (HPOG) program.

OMB No.: 0970–0394.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) is proposing data collection activities as part of the Health Profession Opportunity Grants (HPOG) program. ACF has developed a multi-pronged research and evaluation approach for the HPOG program to better understand and assess the activities conducted and their results. The proposed data collection activities described in this notice will provide data for three evaluation components, the National Implementation Evaluation of the Health Profession Opportunity Grants to Serve TANF Recipients and Other Low-Income Individuals (HPOG–NIE) and the Impact Studies of the Health Profession Opportunity Grants (HPOG-Impact), and the Innovative Strategies for Increasing Self Sufficiency (ISIS) evaluation.

Two data collection efforts related to HPOG research were approved by OMB, including approval of a Performance Reporting System (PRS) (approved September 2011) and for collection of additional baseline data for the HPOG-Impact study (approved October 2012). One data collection of ISIS was approved (November 2011) and follow up data collection instruments are currently under review.

This 60-day notice describes the remaining data collection efforts for both HPOG–NIE and HPOG-Impact. Two of the proposed instruments will collect data from all of the ISIS sites. Information collection described under 1 through 9 will be included in the next OMB submission for review. Information collections 10 through 14 will be submitted in a future information collection clearance request.

The goal of HPOG–NIE is to describe and assess the implementation, systems change, and outcomes and other important information about the operations of the 27 HPOG grantees focused on TANF recipients and other low-income individuals. To achieve these goals, it is necessary to collect data about the HPOG program designs and implementation, HPOG partner and program networks and indicators of systems change, employers' perceptions of HPOG programs, the composition and intensity of HPOG services received, participant characteristics and HPOG experiences, and participant outputs and outcomes.

The goal of HPOG-Impact is to evaluate the effectiveness of approaches used by 20 of the HPOG grantees to provide TANF recipients and other low-income individuals with opportunities for education, training and advancement within the health care field. HPOG-Impact also is intended to evaluate variation in participant impact that may be attributable to different HPOG program components and models. The impact study design is a classic experiment in which eligible applicants will be randomly assigned to a treatment group that is offered participation in HPOG and a control group that is not permitted to enroll in HPOG. Data collected from the HPOG participants served by these 20 grantees will also be used for the HPOG–NIE study.

The goal of ISIS is to test a range of promising career pathways strategies to promote education, employment, and self-sufficiency. Three HPOG grantees are in the ISIS evaluation along with 6 additional non-HPOG sites.

The information collection activities to be submitted in the next request package include:

(1) *The HPOG–NIE sample frame questionnaire* will ask respondents from each of the 27 TANF and low-income HPOG grantees to identify and provide contact information for potential respondents to the surveys described in items 2–4.

(2) *The HPOG–NIE grantee survey* will be administered to staff of the 27 TANF and low-income HPOG grantees and their major collaborators. The survey will collect information about the HPOG program context and about program administration, activities and services.

(3) *The HPOG–NIE survey of HPOG program management and staff* will collect information from HPOG staff in the 27 TANF and low-income HPOG grantee sites about their approaches to delivering key program services and activities, as well as beliefs and attitudes about the HPOG program and mission and priorities in serving its target population.

(4) *The HPOG–NIE stakeholder/network survey* will collect information about partner organizations' and stakeholders' roles, responsibilities, levels of investment, and perceptions of the viability and productivity of the program and stakeholder network in all 27 TANF and low-income HPOG grantee sites and the 6 additional non-HPOG ISIS sites.

(5) *The HPOG–NIE employer survey* will collect information about employers' perceptions of the overall healthcare labor market, firm-specific conditions and hiring practices, and their perceptions of and experience with the program in all 27 TANF and low-income HPOG grantee sites and the 6 additional non-HPOG ISIS sites.

(6) *HPOG-Impact in-person implementation interviews with HPOG personnel* will collect information about the grantees' rationale for applying for HPOG funding, administrative challenges, and challenges implementing programs as planned, as well as information about staff roles and responsibilities and perceptions of the program. The study will use the interviews to supplement and validate sections of the HPOG–NIE grantee survey (described above) in the 27 TANF and low-income HPOG grantee sites.

(7) *HPOG-Impact additional in-person implementation interviews with HPOG personnel at systematic variation grantees* will collect information about the implementation of HPOG program components that may be associated with variation in participant impacts in the 27 TANF and low-income HPOG grantee sites.

(8) *The HPOG-Impact follow-up survey of both treatment and control group members* will be administered approximately 15 months after baseline data collection and random assignment. The survey will collect data about outcomes of interest, including certifications and educational achievements, job placement, wages, and benefits. It also will collect some information about HPOG participants' tenure and experience in HPOG programming in all 20 HPOG Impact sites.

(9) *The HPOG–NIE supplemental participant follow-up survey* will be the same as the instrument developed for the HPOG-Impact follow-up survey but will be administered to participants from the four HPOG grantees focused on TANF recipients and other low-income individuals that are not included in the HPOG-Impact study or the Innovative Strategies for Increasing Self-Sufficiency (ISIS) project.

Data collection activities to submit in a future information collection request include: (10) *The HPOG–NIE follow-up stakeholder/network survey;* (11) *the HPOG-Impact second follow-up survey of both treatment and control group members;* (12) *the HPOG–NIE second supplemental participant follow-up survey;* (13) *HPOG-Impact follow-up data collection on children of HPOG-Impact study participants;* and (14) *the HPOG–NIE in-person interviews with HPOG managers and staff.*

Respondents: Individuals enrolled in HPOG interventions; control group members; HPOG program managers; HPOG program staff, including instructors and case managers; representatives of partner agencies and stakeholders, including support service providers, education and vocational training providers, Workforce Investment Boards, TANF agencies, and local health care employers.

ANNUAL RESPONSE BURDEN ESTIMATES

[This information collection request is for a two-year period]

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
1. HPOG–NIE sample frame questionnaire	54	1	4	216	108
2. HPOG–NIE grantee survey	135	1	0.67	90	45
3. HPOG–NIE survey of HPOG program management and staff	540	1	0.5	270	135
4. HPOG–NIE stakeholder/network survey	610	1	0.5	305	153
5. HPOG–NIE employer survey	244	1	0.5	122	61
6. HPOG-Impact in-person implementation interviews with HPOG personnel	216	1	1	216	108
7. HPOG-Impact additional in-person implementation interviews with HPOG personnel at systematic variation grantees	100	1	1	100	50
8a. HPOG-Impact follow-up survey of HPOG participants	3,416	1	.75	2562	1281
8b. HPOG-Impact follow-up survey of control group members	1708	1	0.5	854	427
9. HPOG–NIE supplemental participant follow-up survey	600	1	0.75	450	225

Estimated Annual Response Burden Hours: 2,593.

In compliance with the requirement of section 3506 (c) (2) (A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families (ACF), Department of Health and Human Services, 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 in writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@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,

ACF Reports Clearance Officer.

[FR Doc. 2012–30686 Filed 12–19–12; 8:45 am]

BILLING CODE 4184–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0482]

Guidances for Industry and Investigators on Safety Reporting Requirements for Investigational New Drug Applications and Bioavailability/Bioequivalence Studies, and a Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two guidances for industry and investigators entitled ''Safety Reporting Requirements for INDs and BA/BE Studies'' and ''Safety Reporting Requirements for INDs and BA/BE Studies—Small Entity Compliance Guide.'' These guidances are intended to help sponsors and investigators comply with the requirements in the final rule entitled ''Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans,'' published in the **Federal Register** on September 29, 2010 (75 FR 59935). FDA has prepared the Small Entity Compliance Guide in accordance with the Small Business Regulatory Enforcement Fairness Act. It is intended to help small businesses understand and comply with the regulations issued by FDA concerning safety reporting requirements for investigational new drug applications (IND) and bioavailability (BA) and bioequivalence (BE) studies.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidances to the Office of Communications, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance documents.

Submit electronic comments on the guidances 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.

FOR FURTHER INFORMATION CONTACT: Stephanie Shapley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6352, Silver Spring, MD 20993–0002, 301–796–4836; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of two guidances for industry and investigators entitled ''Safety Reporting Requirements for INDs and BA/BE Studies'' and ''Safety Reporting Requirements for INDs and BA/BE Studies—Small Entity Compliance Guide.'' These guidances are intended to help sponsors and investigators comply with the requirements for IND safety reporting and safety reporting for BA and BE studies. In addition, the Small Entity Compliance Guide is intended to help small businesses understand and comply with the regulations issued by FDA concerning the safety reporting requirements for INDs and BA/BE studies. FDA has prepared the Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act.

On September 29, 2010, FDA published a final rule amending the IND safety reporting requirements under 21 CFR part 312 and adding safety reporting requirements for persons conducting BA and BE studies under 21 CFR part 320. The requirements in the final rule are intended to improve the utility and quality of safety reports, expedite and strengthen FDA's ability to review critical safety information, and better protect human subjects enrolled in clinical trials. FDA also published a draft guidance entitled ''Safety Reporting Requirements for INDs and BA/BE Studies'' on September 29, 2010 (75 FR 60129), and the public was provided with an opportunity to comment on it until December 28, 2010. FDA carefully considered all of the comments received in developing the final guidance. The final guidance includes clarifications and additional detail regarding the draft guidance topics as well additional information on safety reporting issues raised in the comments.

The final guidance entitled ''Safety Reporting Requirements for INDs and BA/BE Studies'' contains the definitions used for IND safety reporting, makes recommendations on when and how to submit a safety report, and provides advice on other safety reporting issues that have generated questions from sponsors and investigators.

The Small Entity Compliance Guide provides answers to many frequently asked questions FDA has received from investigators and sponsors regarding the safety reporting requirements that are applicable to small entities.

In addition, on June 7, 2011, the Agency published a guidance describing enforcement discretion with the reporting requirements until September 28, 2011, to allow sponsors additional time to make process changes to implement the final rule (76 FR 32863; June 7, 2011). At this time, the Agency is withdrawing this guidance.

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidances represent the Agency's current thinking on safety reporting requirements for IND and BA/BE studies. They do not create or confer any rights for or on any person and do 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.

II. Comments

Interested persons may submit either written comments regarding these documents to the Division of Dockets