1, 2011. A final rule regarding selected provisions of the IFR was published on December 7, 2011 (76 FR 76574, CMS–9998–FC) and an interim final rule regarding an issue not included in issuers' reporting obligations (disbursement of rebates by non-federal governmental plans) was also published December 7, 2011 (76 FR 76596, CMS–9998–IFC2). Both rules published on December 7, 2011 are effective January 1, 2012. Each issuer is required to submit annually MLR data, including information about any rebates it must provide, on a form prescribed by CMS, for each State in which the issuer conducts business. Each issuer is also required to provide a rebate notice to each enrollee that is due a rebate payment for any given MLR reporting year. Additionally, each issuer is required to maintain for a period of seven years all documents, records and other evidence that support the data included in each issuer's annual report to the Secretary.

The original 60-day comment period began on December 16, 2011 and pertained to the MLR Annual Reporting Form, and closed on February 14, 2012. On February 16, we published an amended PRA package with Notices to Consumers and reopened the public comment period until March 2, 2012 to accommodate comments on the amendments to the PRA package. We received a total of 15 public comments regarding the Annual Reporting Form and 11 public comments regarding the Notices to Consumers and Instructions for these notices. Most public comments addressed multiple issues. We have taken into consideration all the proposed suggestions and have made changes to the Annual Reporting Form and Instructions, as well as to the Notices to Consumers and Instructions. In addition, CMS is adjusting the estimated burden that correlates with the Rebate Notices and the MLR Information Notices.

Form Number: CMS–10418 (OCN: 0938–New); *Frequency:* Annual submission for each respondent; *Affected Public:* Private Sector: Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 527; *Number of Responses:* 5,530; *Total Annual Hours:* 352,563. (For policy questions regarding this collection, contact Carol Jimenez at (301) 492–4457. For all other issues, call (410) 786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *May 3, 2012.*

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: *OIRA_submission@omb.eop.gov*.

Dated: March 30, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–8080 Filed 4–2–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Study of Coordination of Tribal TANF and Child Welfare Services.

OMB No.: New Collection.

Description: The Study of Coordination of Tribal TANF and Child Welfare Services is sponsored by the Office of Planning, Research and Evaluation (OPRE), Administration for Children and Families of the U.S. Department of Health and Human Services. The study examines the approaches and strategies utilized by tribes and tribal organizations that were awarded the grants for Coordination of Tribal TANF and Child Welfare Services to Tribal Families at Risk of Child Abuse or Neglect.

The descriptive study of these programs that serve tribal communities will document the way in which the tribal grantees are creating and adapting culturally relevant and appropriate approaches, systems, and programs to increase coordination and enhance service delivery to address child abuse and neglect. The study will also document challenges faced and lessons learned to inform the field of practice as well as policymakers and funders at various levels.

The proposed information collection activities consist of semi-structured interviews, conducted at each of the 14 tribal communities, and a grantee feedback survey on the usefulness of periodically held cross-grantee learning events.

Respondents: Program director(s), tribal TANF and child welfare staff and supervisors, program partners, and tribal leaders or elders. The information collection does not include direct interaction with individuals or families that receive the services.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Interview Protocol for Program Staff	9	3	1.5	41
Interview Protocol for TANF and CW Staff	19	3	1	57
Interview Protocol for Tribal or Community Partners	9	3	.75	20
Interview Protocol for Tribal Leaders or Elders	9	3	1	27
Feedback Form for Community of Learning Events	10	5	.15	8

Estimated Total Annual Burden Hours: 153.

In compliance with the requirements of Section 3506(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, 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,

Reports Clearance Officer.

[FR Doc. 2012–7923 Filed 4–2–12; 8:45 am]

BILLING CODE 4184–35–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0508]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Blood Establishment Registration and Product Listing, Form FDA 2830

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Blood Establishment Registration and Product Listing, Form FDA 2830'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *ila.mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On January 4, 2012, the Agency submitted a proposed collection of information entitled ''Blood Establishment Registration and Product Listing, Form FDA 2830'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0052. The approval expires on March 31, 2015. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: March 28, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–7915 Filed 4–2–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0300]

Draft Guidance for Industry on Compliance Policy for Reporting Drug Sample Distribution Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Compliance Policy on Reporting Drug Sample Distribution Information Under the Affordable Care Act.'' This draft guidance is intended to provide information regarding the Agency's implementation of the drug sample transparency reporting provisions of section 6004 of the Patient Protection and Affordable Care Act. The draft guidance notifies entities covered by the reporting obligations in section 6004 that FDA does not intend to object until at least October 1, 2012, if manufacturers and authorized distributors of record (ADRs) do not submit information under those reporting provisions and that the Agency intends to provide notice before revising its exercise of discretion with respect to compliance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by June 4, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the 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 to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), 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 draft guidance document.

Submit electronic comments on the draft 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.

FOR FURTHER INFORMATION CONTACT: Donovan F. Duggan, Jr., Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4288, Silver Spring, MD 20993–0002, 301–796–0584; Paul Loebach, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4268, Silver Spring, MD 20993–0002, 301–796–2173; 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 a draft guidance for industry entitled ''Compliance Policy on Reporting Drug Sample Distribution Information.'' On March 23, 2010, the Affordable Care Act was signed into law. Among its many provisions, section 6004 of the Affordable Care Act amended the Social Security Act by adding section 1128H (42 U.S.C. 1320a–7i). This new section requires the submission of certain drug sample information to FDA not later than April 1 of each year, beginning April 1, 2012.

The draft guidance is intended to provide information regarding the Agency's implementation of section