physician in providing medical orders and medical care services to patients of the clinic or center.

• To meet the requirements at § 491.9(b)(4), TCT revised its standards to address the requirement that patient care policies are reviewed at least annually, and as necessary by the clinic or center.

• To meet the requirements at § 491.9(c)(2), TCT revised its standards to ensure laboratory services are provided in accordance with the requirements at 42 CFR Part 493 and Section 353 of the Public Health Service Act.

• To meet the requirements at § 491.9(d)(1), TCT revised its standards to require the clinic or center have an agreement or arrangement with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients.

• TCT developed an action plan to ensure compliance with its own policies regarding RHCs receiving the correct accreditation date on their notice of survey results.

• To meet the requirements at § 488.4(a)(6), TCT revised its policies to ensure timeframes for investigation of complaints are comparable with the requirements in section 5075.9 of the State Operations Manual.

• To meet the requirements at § 489.13(b), TCT revised its policies to clarify that the effective date of the agreement or approval is determined by the CMS Regional Office and may not be earlier than the latest of the dates of which CMS determines that all applicable federal requirements are met. TCT revised all Clinic Advisor On-Site Worksheets to include a descriptive title for the requirement of each worksheet for increased clarity.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that TCT's RHC accreditation program requirements meet or exceed our requirements. Therefore, we approve TCT as a national accreditation organization for RHCs that request participation in the Medicare program, effective July 18, 2014 through July 18, 2018.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

Dated: July 8, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–16735 Filed 7–17–14; 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

Proposed Projects

Title: Child Care Quarterly Case Record Report—ACF–801.

OMB No.: 0970–0167.

Description: Section 658K of the Child Care and Development Block Grant Act of 1990 (P.L. 101–508, 42 U.S.C. 9858) requires that States and Territories submit monthly case-level data on the children and families receiving direct services under the Child Care and Development Fund. The implementing regulations for the statutorily required reporting are at 45 CFR 98.70. Case-level reports, submitted quarterly or monthly (at grantee option), include monthly sample or full population case-level data. The data elements to be included in these reports are represented in the ACF–801. ACF uses disaggregate data to determine program and participant characteristics as well as costs and levels of child care services provided. This provides ACF with the information necessary to make reports to Congress, address national child care needs, offer technical assistance to grantees, meet performance measures, and conduct research. Consistent with the statute and regulations, ACF requests extension of the ACF–801 without changes.

Respondents: States, the District of Columbia, and Territories including Puerto Rico, Guam, the Virgin Islands, American Samoa, and the Northern Marianna Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–801	56	4	25	5,600

Estimated Total Annual Burden Hours: 5,600.

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, 370 L'Enfant Promenade SW., Washington, DC 20447, 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.

[FR Doc. 2014–16922 Filed 7–17–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0903]

Draft Guidance for Industry: Providing Submissions in Electronic Format—Postmarketing Safety Reports for Vaccines; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Providing Submissions in Electronic Format—Postmarketing Safety Reports for Vaccines'' dated July 2014. The draft guidance document provides information and recommendations pertaining to the electronic submission of postmarketing safety reports involving vaccine products marketed for human use with approved biologics license applications (BLAs), including individual case safety reports (ICSRs) and attachments to ICSRs (ICSR attachments), into the Vaccine Adverse Event Reporting System (VAERS). FDA recently published in the **Federal Register** a final rule requiring that certain postmarketing safety reports for human drug and biological products, including vaccines, be submitted to FDA in an electronic format that the Agency can process, review, and archive. The draft guidance, when finalized, is intended to help applicants required to submit postmarketing safety reports comply with the final rule. The draft guidance, when finalized, also will supersede the document entitled ''Guidance for Industry: How to Complete the Vaccine Adverse Event Report System Form (VAERS–1)'' dated September 1998.

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 either electronic or written comments on the draft guidance by September 16, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. 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: John Reilly, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Providing Submissions in Electronic Format—Postmarketing Safety Reports for Vaccines'' dated July 2014. The draft guidance provides information and recommendations pertaining to the electronic submission of postmarketing safety reports involving vaccine products, including ICSRs and ICSR attachments, into VAERS. The guidance is applicable to vaccine products marketed for human use with approved BLAs for which CBER has regulatory responsibility. This guidance does not apply to any other biologic product.

In the **Federal Register** of June 10, 2014 (79 FR 33072), FDA published a final rule requiring that certain postmarketing safety reports for human drug and biological products, including vaccines, be submitted to FDA in an electronic format that the Agency can process, review, and archive. The draft guidance, when finalized, is intended to help applicants subject to postmarketing safety reporting requirements comply with the final rule. Along with other information, the draft guidance provides updated information about the following: (1) Options for submitting ICSRs and ICSR attachments, as well as other postmarketing safety reports to FDA in electronic format, (2) the notification sent to submitters when FDA has received the electronic postmarketing safety report, and (3) procedures for requesting temporary waivers from the electronic submission requirement. The draft guidance, when finalized, also will supersede the document entitled ''Guidance for Industry: How to Complete the Vaccine Adverse Event Reporting System Form (VAERS–1)'' dated September 1998.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The information collection resulting from this draft guidance is covered by the information collection provisions of the June 10, 2014, final rule entitled ''Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements.'' The information collection provisions of the final rule have been submitted to the Office of Management and Budget (OMB) for review, as required under section 3507(d) of the Paperwork Reduction Act. Prior to the effective date of the final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule. 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.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.