DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS–224–14]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by July 25, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Federally Qualified Health Center Cost Report Form; *Use:* The Form CMS–224–14 cost report is needed to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and to calculate the FQHC settlement amount. These providers, paid under the FQHC prospective payment system (PPS), may receive reimbursement outside of the PPS for Medicare reimbursable bad debts, pneumococcal, influenza, and COVID–19 vaccines, and monoclonal antibody products. CMS uses the Form CMS–224–14 for rate setting; payment refinement activities, including developing a FQHC market basket; Medicare Trust Fund projections; and to support program operations. Additionally, the Medicare Payment Advisory Commission (MedPAC) uses the FQHC Medicare cost report data to calculate Medicare margins; to formulate recommendations to Congress regarding the FQHC PPS; and to conduct additional analysis of the FQHC PPS. *Form Number:* CMS–224–14 (OMB control number: 0938–1298); *Frequency:* Yearly; *Affected Public:* Private Sector, State, Local, or Tribal Governments, Federal Government, Business or other for-profits, Not-for-Profit Institutions; *Number of Respondents:* 2,890; *Total Annual Responses:* 2,890; *Total Annual Hours:* 167,620. (For policy questions regarding this collection contact LuAnn Piccione at 410–786–5423.)

Dated: June 21, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–13551 Filed 6–23–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Tribal Consultation Meetings

AGENCY: Office of Head Start (OHS), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS).

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Head Start Act, notice is hereby given of three tribal consultation sessions to be held between HHS/ACF OHS leadership and the leadership of tribal governments operating Head Start and Early Head Start programs. The purpose of these consultation sessions is to discuss ways to better meet the needs of American Indian and Alaska Native (AI/AN) children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. Three tribal consultations will be held as part of HHS/ACF or ACF Tribal Consultation Sessions.

DATES:

Tuesday, July 12, 2022
Monday, August 15, 2022
Wednesday, September 14, 2022

ADDRESSES:

- July 12, 2022—3–5 p.m. ET (Virtual)
- August 15, 2022—1–5 p.m. PT (Northern Quest Resort & Casino, 100 N Hayford Rd., Airway Heights, WA 99001)
- September 14, 2022—2–5 p.m. ET (Virtual)

FOR FURTHER INFORMATION CONTACT: Todd Lertjuntharangool, Regional Program Manager, Region XI/AIAN, Office of Head Start, email *Todd.Lertjuntharangool@acf.hhs.gov,* or phone (866) 763–6481. Additional information and online meeting registration will be available here.

SUPPLEMENTARY INFORMATION: In accordance with Section 640(l)(4) of the Head Start Act, 42 U.S.C. 9835(1)(4), ACF announces OHS Tribal Consultation Sessions for leaders of

tribal governments operating Head Start and Early Head Start programs.

The agenda for the scheduled OHS Tribal Consultations reflects the statutory purposes of Head Start tribal consultations related to meeting the needs of AI/AN children and families. OHS will also highlight the progress made in addressing issues and concerns raised in the previous OHS Tribal Consultations.

The consultation sessions include elected or appointed leaders of tribal governments and their designated representatives. Designees must have a letter from the tribal government authorizing them to represent the tribe. Tribal governments must submit the designee letter at least 3 days before the consultation sessions to Todd Lertjuntharangool at *Todd.Lertjuntharangool@acf.hhs.gov.* Other representatives of tribal organizations and Native nonprofit organizations are welcome to attend as observers.

Within 45 days of the consultation sessions, a detailed report of each consultation session will be available for all tribal governments receiving funds for Head Start and Early Head Start programs. Tribes can submit written testimony for the report to Todd Lertjuntharangool at *Todd.Lertjuntharangool@acf.hhs.gov* prior to each consultation session or within 30 days of each meeting. OHS will summarize oral testimony and comments from the consultation sessions in each report without attribution, along with topics of concern and recommendations.

Roshelle M. Brooks,

ACF Certifying Officer.

[FR Doc. 2022–13532 Filed 6–23–22; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Notice of Federal Review of the American Samoa Protection and Advocacy System (P&A)

AGENCY: Administration for Community Living, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: Representatives of the Administration on Disabilities (AoD), Administration for Community Living (ACL), will be conducting a federal review of the American Samoa Protection and Advocacy System (P&A) on September 19–23, 2022. AoD is soliciting comments from interested parties on your experiences with the program, and strategies employed by P&A in meeting the needs of individuals with developmental disabilities and their families in American Samoa. You are encouraged to share your experiences by way of any of the following methods:

DATES: Comments should be received by September 1, 2022 in order to be included in the final report.

ADDRESSES: EMAIL: *Elizabeth.leef@acl.hhs.gov,* TELEPHONE: 202–475–2482, MAIL COMMENTS TO: Elizabeth Leef, Program Specialist, Administration on Disabilities, Administration for Community Living, 330 C Street SW, 1st Floor, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Elizabeth Leef, Administration for Community Living, Administration on Disabilities, 330 C Street SW, 1st Floor, Washington, DC 20201, 202–475–2482.

Authority: 45 CFR 1326.21(h)

Dated: June 15, 2022.

Alison Barkoff,

Acting Administrator & Assistant Secretary for Aging.

[FR Doc. 2022–13462 Filed 6–23–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3815]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishment Registration and Device Listing for Manufacturers and Importers of Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 25, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0625. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Establishment Registration and Device Listing for Manufacturers and Importers of Devices—21 CFR Part 807, Subparts A Through D

OMB Control Number 0910–0625—Extension

Under section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360) and implementing regulations in 21 CFR part 807, subparts A through D (part 807, subparts A through D), medical device establishment owners and operators are required to electronically submit establishment registration and device listing information. Complete and accurate registration and listing information is necessary to accomplish a number of statutory and regulatory objectives, such as: (1) identification of establishments producing marketed medical devices; (2) identification of establishments producing a specific device when that device is in short supply or is needed for national emergency; (3) facilitation of recalls for devices marketed by owners and operators of device establishments; (4) identification and cataloging of marketed devices; (5) administering postmarketing surveillance programs for devices; (6) identification of devices marketed in violation of the law; (7) identification and control of devices imported into the country from foreign establishments; and (8) scheduling and planning inspections of registered establishments under section 704 of the FD&C Act (21 U.S.C. 374).

Respondents to this information collection are owners or operators of establishments that engage in the manufacturing, preparation, propagation, compounding, or processing of a device or devices, who must register their establishments and