NAM CAHPS surveys. The population-specific questionnaire module will collect information about issues most relevant for particular minority groups; population-specific modules will be described in individual information collection requests. These data will be compared to benchmarks from the relevant CAHPS source surveys when available.

Collection of these data from people who have been identified through CMS administrative data and administrative flags as part of specific minority populations will also serve as a critical validation step of this method for identifying difficult-to-study populations, thus making it easier to study beneficiaries in these groups in the future. *Form Number:* CMS–10701 (OMB control number: 0938–NEW); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 10,000; *Total Annual Responses:* 10,000; *Total Annual Hours:* 3,333. (For policy questions regarding this collection contact Luis Perez at 410–786–8557.)

2. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Medicare Parts C and D Program Audit Protocols and Data Requests; *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR parts 422 and 423, Medicare Part D plan sponsors and Medicare Advantage organizations are required to comply with all Medicare Parts C and D program requirements. CMS' annual audit plan ensures that we evaluate sponsoring organizations' compliance with these requirements. CMS program audits focus on high-risk areas that have the greatest potential for beneficiary harm. As such, CMS has developed several audit protocols that are included within the program area data request documents and that are posted to the CMS website each year for use by sponsoring organizations to prepare for their audit. As part of a robust audit process, CMS also requires sponsoring organizations who have been audited and found to have deficiencies to undergo a validation audit to ensure correction. The validation audit utilizes the same audit protocols, but only tests the elements where deficiencies were found, as opposed to re-administering the entire audit.

Currently CMS utilizes the following 5 protocols to audit sponsoring organization performance: Part D Formulary and Benefit Administration (FA); Part D Coverage Determinations, Appeals, and Grievances (CDAG); Part C Organization Determinations, Appeals, and Grievances (ODAG); Special Needs Model of Care (SNP–MOC) (only administered on organizations who operate SNPs); and, Compliance Program Effectiveness (CPE). The data collected is detailed in each of these protocols and the exact fields are located in the record layouts, at the end of each protocol. In addition, this collection request includes a pre-audit issue summary, three CPE questionnaires, one CPE organizational structure presentation template, one FA impact analysis template, two CDAG impact analysis templates, four ODAG impact analysis templates, three SNP–MOC impact analysis templates, and a SNP–MOC questionnaire.

The information gathered during this audit will be used by the Medicare Parts C and D Oversight and Enforcement Group (MOEG) within the Center for Medicare (CM) and CMS Regional Offices to assess sponsoring organizations' compliance with Medicare program requirements. If outliers or other data anomalies are detected, Regional Offices will work in collaboration with MOEG and other divisions within CMS for follow-up and resolution. Additionally, MA and Part D organizations will receive the audit results and will be required to implement corrective action to correct any identified deficiencies. *Form Number:* CMS–10191 (OMB control number: 0938–1000); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 201; *Total Annual Responses:* 207; *Total Annual Hours:* 39,456. (For policy questions regarding this collection contact Brenda Hudson at 443–743–9299.)

3. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), and implementing regulations at 42 CFR, Medicare Advantage organizations (MAOs) and Prescription Drug Plans (PDPs) are required to submit an actuarial pricing ''bid'' for each plan offered to Medicare beneficiaries for approval by the Centers for Medicare & Medicaid Services (CMS).

Medicare Advantage organizations (MAO) and Prescription Drug Plans (PDP) are required to submit an actuarial pricing ''bid'' for each plan offered to Medicare beneficiaries for approval by CMS. The MAOs and PDPs use the Bid Pricing Tool (BPT) software to develop their actuarial pricing bid. The competitive bidding process defined by the ''The Medicare Prescription Drug, Improvement, and Modernization Act'' (MMA) applies to both the MA and Part D programs. It is an annual process that encompasses the release of the MA rate book in April, the bid's that plans submit to CMS in June, and the release of the Part D and RPPO benchmarks, which typically occurs in August. *Form Number:* CMS–10142 (OMB control number: 0938–0944); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 555; *Total Annual Responses:* 4995; *Total Annual Hours:* 149,850. (For policy questions regarding this collection contact Rachel Shevland at 410–786–3026.)

Dated: December 20, 2019.

William N. Parham, III,

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

[FR Doc. 2019–27926 Filed 12–26–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Numbers: 93.581, 93.587, 93.612]

Notice for Public Comment on Administration for Native Americans' Program Policies and Procedures

AGENCY: Administration for Native Americans (ANA), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice for public comment.

SUMMARY: Pursuant to Section 814 of the Native American Programs Act of 1974 (NAPA), as amended, the ANA is required to provide members of the public an opportunity to comment on proposed changes in interpretive rules and general statements of policy and to give notice of the proposed changes no less than 30 days before such changes become effective. In accordance with notice requirements of NAPA, ANA herein describes proposed interpretive rules and general statements of policy that relate to ANA's funding opportunities in Fiscal Year (FY) 2020. Changes to FY 2020 Funding Opportunity Announcements (FOAs) will be based on the following previously published programs: Environmental Regulatory Enhancement (ERE), HHS–2018–ACF–ANA–NR–1344; Native American Language Preservation

and Maintenance—Esther Martinez Immersion (EMI), HHS–2018–ACF–ANA–NB–1343; Native American Language Preservation and Maintenance (P&M), HHS–2018–ACF–ANA–NL–1342; Social and Economic Development Strategies (SEDS), HHS–2018–ACF–ANA–NA–1339; Social and Economic Development Strategies—Alaska (SEDS–AK), HHS–2018–ACF–ANA–NK–1340. In addition, ANA will publish a new FOA, HHS–2020–ACF–ANA–NN–1837, which will be titled Social and Economic Development Strategies for Growing Organizations (SEDS–GO). More information about SEDS–GO will be published in a separate **Federal Register** Notice.

DATES: Comments are due by January 27, 2020. If ANA does not receive any significant comments within the 30 day comment period, ANA will proceed with the proposed changes in the respective published FOAs. The FOAs will serve as the final notice of these proposed changes.

ADDRESSES: Comments may be submitted to: Carmelia Strickland, Director of Program Operations, Administration for Native Americans, 330 C Street SW, Washington, DC 20201 or via email: *ANAComments@acf.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Carmelia Strickland, Director, Division of Program Operations, Administration for Native Americans, 330 C Street SW, Washington, DC 20201. Telephone: (877) 922–9262; Email: *ANAComments@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 814 of NAPA, as amended, (42 U.S.C. 2992b–1) incorporates provisions of the Administrative Procedure Act that require ANA to provide notice of its proposed interpretive rules and statements of policy and to seek public comment on such proposals. This notice serves to fulfill the statutory notice and public comment requirement. ANA voluntarily includes rules of practice and procedures in this notice in an effort to be transparent. The proposed interpretive rules, statements of policy, and rules of ANA practice and procedure reflected in clarifications, modifications, and new text will appear in the six FY 2020 FOAs: ERE, EMI, P&M, SEDS, SEDS–AK, and SEDS–GO.

ANA's past FOAs can be accessed at: *http://www.acf.hhs.gov/grants/open/foa/office/ana* or *http://www.acf.hhs.gov/grants/open/foa/.* Synopses and application forms will be available on *https://www.grants.gov.*

A. *Interpretive rules, statements of policy, procedures, and practice.* The proposals below reflect ANA's proposed changes in rules, policy, or procedure which will take effect in the FY 2020 FOAs.

1. Making the ANA grant application process easier—To address applicant feedback about applying for an ANA grant, the proposed changes will be made to simplify the process to the extent possible for eligible applicants by (i.) exempting ANA applications from the ACF two-file requirement, (ii.) changing how to upload the Objective Work Plan (OWP) and (iii.) providing staggered application deadlines.

i. ANA proposes to exempt applicants from the ACF standard two-file upload requirement when applying to all FY 2020 ANA FOAs in order to reduce the technical expertise and software required to combine multiple documents and files into only two-files. The 150 page limit remains in effect.

ii. ANA proposes to make the OWP form an ''Optional'' form in the application packages for each FOA. This technical change will allow applicants to submit the OWP form available in ANA's Application Toolkit or on *Grants.gov.* ANA's OWP form is available on the *Grants.gov* website as well as in the ANA Application Toolkit, which can be found on the ANA website. Although the form will still be required as part of a complete application, this change will help applicants to submit the form in whatever version they utilized to prepare the application rather than prescribing the use of the *Grants.gov* version.

iii. Finally, ANA proposes to publish the FOAs for EMI, P&M, and ERE first and then allow a two week period before the SEDS and SEDS–AK are published. The SEDS–GO FOAs may be published with the other SEDS FOAs or at a later date. Therefore, the application submission deadlines will also be staggered accordingly. ANA's intent for making these changes is to make applying for ANA funding easier for our Native communities and more accessible to ANA's eligible applicants.

2. *Application Requirements and Evaluation Criteria Scores*—Sections 803 and 806 of NAPA, 42 U.S.C. 2991b; 2991d–1. In FY 2018, ANA made substantial revisions to the application requirements and evaluation criteria included in our FOAs. The purpose of the revisions was to shift from a deficit-based to a strengths-based approach for application planning and development, as well as to emphasize a community-based approach to project planning and implementation. ANA stands behind the revisions made in FY 2018 and does not plan to change the information being requested. However, during the panel review process, ANA received feedback that the evaluation criteria was difficult to understand and redundant. Additionally, the ACF Uniform Project Description, which is the template used to prepare all ACF FOAs in accordance with the Paperwork Reduction Act (44 U.S.C. 3501–3521) was updated last year. To remain consist with our Application requirements and structure, ANA will move the ANA Project Framework, which was originally under Expected Outcomes, into the Approach section. ANA proposes the following Evaluation criteria scores for FY 2020:

Approach for a maximum of 76 points, to consist of: The ANA Project Framework: Long Term Community Goal (2 points), Current Community Condition (3 points), Project Goal (3 points), Objectives (6 points) Outcomes and Indicators (6 points), Outputs (4 points); Outcome Tracker and Outcome Tracking Strategy (7 points); Community-Based Strategy (10 points); Readiness and Implementation Strategy (20 points); and the Objective Work Plan (OWP) (15 points).

Organizational Capacity (12 points), to also consist of: Personnel and Partnerships.

Budget and Budget Justification for a maximum of 12 points, to consist of: Line Item Budget (4 points) and the narrative Budget Justification (8 points).

These changes are meant to streamline the information required for a successful grant application and provide smaller point allotments in order to make ANA's evaluation criterion more approachable. In addition, it is intended to provide greater guidance to panel reviewers on how to allocate scores.

3. *Changes to the SEDS–FOA: Commissioner priorities and bonus points*—Sections 803 and 803B of NAPA, 42 U.S.C. 2991b; 2991b–2. ANA Commissioner Jean Hovland has identified several priority areas that she would like to potentially fund through the SEDS program. Therefore, 5 bonus points will be available for applications that address one of the following priority areas: Elders, Veterans, First Responders, Murdered and Missing Indigenous Women (MMIW), and/or Human Trafficking. Applications that address one of more of these priorities areas should be reflected in the project goal, all objectives, indicator(s), and target population (either as participants or beneficiaries). Reviewers will provide 5 points if all elements are included in the application to address one or more priority areas. In addition, the program areas of interest will be expanded to include opportunity zones under economic competitiveness, and smoking and vaping under substance abuse prevention.

4. *Changes to SEDS–AK FOA*—Section 803 of NAPA, 42 U.S.C. 2991b.

ANA plans to modify the description of program purpose for the SEDS–AK FOA to expand the program areas of interest beyond governance. In addition, ANA wants to provide a competitive advantage for smaller Alaska Native villages or organizations that have never received ANA funding. Therefore, the FOA will state that reviewers may add up to 10 bonus points in the scoring criteria if an eligible entity that has never received an ANA award. ANA staff will confirm during the objective review process whether or not an applicant organization for SEDS–AK has received a past ANA award.

a. *Changes to EMI FOA*—Section 803C of NAPA, 42 U.S.C. 2991b–3. In accordance with 42 U.S.C. 2991b–3(c)(7), applicants for an EMI grant must provide a certification that the organization has not less than 3 years of experience in operating and administering a Native American language survival school, a Native American language nest, or any other educational program in which instruction is conducted in a Native American language. Previously, this requirement only applied to Native American language survival schools. ANA will now require all applicants for EMI to provide a certification of operation of not less than 3 years.

b. *Clarification to ERE FOA*—Section 803 of NAPA, 42 U.S.C. 2991b.

i. Section 803(d)(3) of NAPA (42 U.S.C. 2991b(d)(3)) permits Federal funds to be used as cost sharing or matching funds for an ERE project, as long as they are not provided from other ANA grants. Therefore, ANA will add this clarification in the ERE FOA. Before using Federal grant funds as matching funds, grantees must make sure that the authorizing statute for the matching Federal grant funds specifically allows its grant funds to be used as cost share or matching funds.

ii. ANA will also permit entities to apply for ERE grants even if they do not own land. There is no requirement within the provisions for ERE under NAPA that require the eligible entity to own land. Applications will be evaluated in accordance with the evaluation criteria in the FOA, including ensuring the purpose of the ERE program will be met.

Statutory Authority: Section 814 of the Native American Programs Act of 1974 (NAPA), as amended.

Jean Hovland,

Commissioner, Administration for Native Americans, Administration for Children and Families.

[FR Doc. 2019–27916 Filed 12–26–19; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2434]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Formal Meetings Between the Food and Drug Administration and Sponsors and Applicants of Prescription Drug User Fee Act Products

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 January 27, 2020.

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 0910–0429. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Formal Meetings Between FDA and Sponsors and Applicants of Prescription Drug User Fee Act Products

OMB Control Number 0910–0429—Reinstatement

This information collection supports implementation of the Prescription Drug User Fee Amendments (PDUFA) of the FDA Reauthorization Act of 2017 (FDARA). Consistent with Agency regulations and provisions found in our ''Reauthorization Performance Goals And Procedures: Fiscal Years 2018 Through 2022,'' we have established procedural guidance pertaining to formal meetings between FDA and sponsors or applicants of certain drug or biological drug products regulated by the Center for Drug Evaluation (CDER) and Research and the Center for Biologics Evaluation and Research (CBER). Because these meetings often represent critical points in the regulatory process, we intend these recommendations to facilitate the timely and effective scheduling of such meetings, as well as ensure their efficiency and appropriate documentation.

While FDA regulations in 21 CFR 10.65, 312.47, 314.50, and 314.102 describe general considerations and set forth certain information collection elements pertaining to meetings with FDA, the guidance document entitled, ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products,'' discusses specific topics for sponsors of PDUFA products such as types of meetings, meeting formats, meetings requests, FDA response, and meeting packages. The guidance recommendations do not apply to abbreviated new drug applications, applications for biosimilar biological products, or submissions for medical devices. Issued consistent with our Good Guidance Practice regulations in 21 CFR 10.115, we originally developed the guidance in 1999 and it has since undergone various revisions to reflect reauthorization of relevant user fee legislation. The guidance explains our recommendations with regard to PDUFA meetings and that the following elements be included in a meeting request to FDA:

- Information identifying and describing the product;
- the type of meeting being requested; a brief statement of the purpose of the meeting;
- a list of objectives and expected outcomes from the meeting;
- a preliminary proposed agenda; a draft list of questions to be raised at the meeting;
- a list of individuals who will represent the sponsor or applicant at the meeting;
- a list of Agency staff requested to be in attendance;
- the approximate date that the information package will be sent to the Agency;
- and suggested dates and times for the meeting.

We use the information to determine the purpose of the meeting and to