

must submit documentation that identifies each board member by name and indicates his/her affiliation or relationship to at least one of ANA's three categories of community representation, which include: (1) Members of federally or state-recognized tribes; (2) persons who are recognized by members of the eligible Native American community to be served as having a cultural relationship with that community; or (3) persons considered to be Native American as defined in 45 CFR 1336.10 and Native American Pacific Islanders as defined in Section 815 of NAPA. ANA wishes to clarify that the second category of community representation requires a "cultural" relationship defined as lineage, familial, marriage, or other traditional or social connection to the community and not a business or work relationship, (e.g. person that owns a business or is employed by an organization that serves the Native community). Applicants that do not include this documentation will be considered non-responsive, and the application will not be considered for competition.

3. Only One Active Award Per CFDA Number. ANA has a long-standing policy that organizations can have no more than one active award per Catalog of Federal Domestic Assistance (CFDA) number for an ANA program at any given time. SEDS, SEDS-AK, Native Assets Building Initiative (NABI), and ILEAD have the same CFDA number 93.612. From FY 2016 to FY 2018, ANA allowed an exception for organizations that were applying for the ILEAD FOA to also have an award for SEDS, SEDS-AK, or NABI even though they had the same CFDA number as ILEAD. For FY 2019, this exception will not be available to any currently funded ILEAD grantees; therefore, the policy will remain effective to limit the number of awards an organization can have under a single CFDA number. This policy change will allow other Native communities without current ANA funding to receive an award and therefore increase the impact of funding in more communities.

4. Evaluation Criteria. In FY 2018, ANA made substantial revisions to the application requirements and evaluation criteria included in our FOAs. The purpose of these revisions were to shift from a deficit-based, to 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 revised evaluation criteria was difficult to understand and apply. In FY 2019, ANA will reorder the evaluation criteria and include sub-criteria with smaller point allotments. We will also remove duplications and clarify language. ANA proposes the following Evaluation criteria scores for FY 2019:

Expected Outcomes for a maximum of 35 points, to consist of: Long Term Community Goal (2 points), Current Community Condition (5 points); Project Goal (4 points); Objectives (7 points); Outcomes and Indicators (7 points); Outputs (5 points); Outcome Tracking Strategy (4 points); and Outcome Tracker (1 point).

Approach for a maximum of 50 points, to consist of: Planning, Readiness and Implementation Strategy (20 points); Community-Based Strategy (8 points); Personnel, Partnerships and Organizational Capacity (12 points); and the Objective Work Plan (OWP) (10 points).

Budget and Budget Justification for a maximum of 15 points, to consist of: Line Item Budget (5 points) and Budget Justification (10 points).

These changes are meant to reorganize the information into smaller point allotments in order to make ANA's evaluation criterion more approachable, and to build consistency in the number of points being allocated for specific application information. As a result of the changes to criteria scoring, ANA will not use a Scoring Guide in its FY 2019 FOAs.

5. Changes to SEDS-AK FOA. ANA plans to modify the description of program purpose for the SEDS-AK FOA to provide an area of interest for economic growth. 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 5 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.

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

Jean Hovland,

Commissioner, Administration for Native Americans.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Data Exchange Standards for Improved Interoperability of Multiple Human Service Programs

AGENCY: Office of Planning, Research & Evaluation (OPRE), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Request for comments.

SUMMARY: A series of statutory changes¹ in recent years require ACF to issue a regulation to establish standards for data exchange for the Social Security Act Title IV programs for child welfare and foster care (title IV-B and IV-E), child support (title IV-D), and Temporary Assistance for Needy Families (TANF, title IV-A). ACF is seeking public comment on the most effective approaches and technological tools to meet the statutory requirements, support program objectives, and expand the ability of these programs to use, share, and analyze data for improved outcomes.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section below on or before January 7, 2019.

ADDRESSES: Interested persons may submit written comments by any of the following methods:

- Email: DataRx@acf.hhs.gov. Please include "Comments on Data Exchange Standards **Federal Register** Notice" in the subject line of the message.
- Mail or Courier Delivery: c/o Chris Traver, Senior Advisor, Division of Data & Improvement, Office of Planning, Research, and Evaluation, Administration for Children and Families, 330 C Street SW, Washington, DC 20201.

Instructions: We urge you to submit comments electronically to ensure they are received in a timely manner. All comments received may be posted publicly including any personal information provided. Please be aware that mail via the U.S. Postal Service may take an additional 3 to 4 days to process. If you choose to use an express, overnight, or other special delivery method, please ensure first that they are

¹ Public Law 112-34 for child welfare programs (SSA Title IV-B); Public Law 112-96 for TANF programs (SSA Title IV-A); Section 304 of Public Law 113-183 for child support programs (SSA Title IV-D); and Public Law 115-123 to amend the prior TANF (IV-A) language and add language for foster care programs (SSA Title IV-E).

able to deliver to the above address during the normal workweek.

FOR FURTHER INFORMATION CONTACT:

Chris Traver, Senior Advisor, Division of Data & Improvement, Office of Planning, Research, and Evaluation, Administration for Children and Families, 330 C Street SW, Washington, DC 20201; (202) 401-4835.

SUPPLEMENTARY INFORMATION:

Background: Purpose of Data Exchange Standardization Requirement.

The purpose of the statutory requirements and corresponding regulation is to ensure that state human service programs are able to effectively share data, both at the state level and with the federal government. For instance, states find significant value in the ability to share or link case level data from one information system to another on the same individuals receiving benefits and/or services in order to support a holistic, wrap-around services approach for individuals and families. To achieve this in an efficient manner, each agency must agree to describe the shared data in a common way. As a simple example, if an agency records in its information system a client's birthdate as 12/11/10, it could be interpreted by another agency's information system as December 11, 2010, and by another agency as November 12, 2010, or something else entirely. Those agencies must also agree on the mechanisms for sharing the data, such as secure interfaces (including APIs)² or file transfers. Therefore, it is critical to reach agreement beforehand regarding the definitions and structures of data that is shared across programs and systems. Under the required regulation, ACF would work with the states to develop and implement data exchange standards for certain categories of information that would improve the quality and consistency of human services data sharing implementation nationwide.

In human services, data sharing is increasingly relied upon to enable coordination across programs and information/system silos, especially for effective integrated case management and prevention of improper payments. For example, if a single mother of two children is receiving a TANF benefit but the two children are subsequently removed and placed into foster care, data sharing across information systems would allow the TANF agency to know that the children are no longer living in the household and the mother may no

longer be eligible for the same level of benefit.

Data sharing also improves the quality of service delivery. For example, a child welfare caseworker might be able to retrieve a family's current address from child support data to locate the family for an in-person visit or locate the absent parent for possible placement of the children. Additionally, a data exchange between a child welfare agency with care and custody of a child and a child-placing agency with physical custody would ensure both agencies have the most current information on the child in care.

The importance of data sharing may be well understood. However, the preferred implementation method may vary by agency. The greater the degree of standardization, the easier it is to share data across organizations. While more effective and cost effective in the long run, this approach requires a standardized format, structure, and methods for sharing the data prior to implementation and may initially introduce additional considerations that influence time and cost. Therefore, the final regulation will seek the appropriate balance between the benefits of standardization and ease of implementation.

Regulation Development

The Office of Planning, Research, and Evaluation (OPRE) will lead the drafting of the regulation with subject matter expertise from the ACF Children's Bureau (CB), Office of Child Support Enforcement (OCSE), and Office of Family Assistance (OFA). Additionally, OPRE will consult with other agencies that may be impacted by the regulation through existing or future data exchange relationships, such as the Centers for Medicare and Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA).

Definitions (for the Purposes of This Request for Comment)

Data Exchange should refer to any sharing of information, whether through transfer of data, expanded access to data, or any other mechanism that increases the utilization of information. Data exchange could include sharing for the purposes of case management, program administration, data reporting, analytics, etc. It is generally thought to refer to exchange of data across program, organizational, or jurisdictional boundaries, but this is not strictly necessary to be considered an exchange of information. In this context, data exchange typically refers to the electronic exchange of data via automated data systems, rather than

through more traditional, often paper-based, means.

Standards should refer to any documented, consistent, and repeatable method for exchanging data, either through technical or non-technical means. There are technical standards for the electronic exchange of data (such as through tools including the National Information Exchange Model (NIEM)),³ and there are also standards of practice in the context of business process. These are often codified in policies, interagency agreements, memoranda of understanding, service-level agreements, etc.

What We Are Looking for in Public Comments

ACF is committed to providing state agencies with flexibility to implement standards for economical, efficient, and effective information systems that support policy and practice. Therefore, we are soliciting comments from interested parties on setting standards for data exchanges that affect the SSA Title IV programs for child welfare and foster care (title IV-B and IV-E), child support (title IV-D), and Temporary Assistance for Needy Families (TANF, title IV-A). But we are also interested in receiving input affecting additional programs. Please comment on any aspects of the planned Data Exchange Standards Regulation that you wish.

We are particularly interested in obtaining responses to the following questions:

1. The ability to share data is often impacted by state or federal law, policies, or other governing frameworks. Are there individual programs or agencies that are particularly impacted by their existence or absence? What are the key enablers and/or barriers to automated data exchange in your program or agency?

2. To what degree, if any, are data exchange efforts negatively impacted by a lack of standardization? In other words, where would greater consistency of data (definitions, format, and structure) help improve existing or planned data exchanges?

3. Have you considered adopting a standards-based approach to data exchange? If so, were any existing standards frameworks (such as the National Information Exchange Model) considered, and what influenced the decision for or against? What are some of the benefits (planned or achieved) of adopting a standards-based approach?

4. What factors should be considered before committing to a standards-based

² Application Programming Interface—<https://www.techopedia.com/definition/24407/application-programming-interface-api>.

³ <https://www.niem.gov/communities/human-services>.

approach to data exchange? This might include timing (procurement, fiscal year, or legislative cycles), cost, availability of required expertise, needed regulatory change, impacts on current practices, etc.

5. If a more standards-based approach to data exchange were adopted, what kinds of technical assistance or training would you anticipate needing, if any?

ACF appreciates any and all comments on the above questions, or related recommendations. Comments will be considered carefully and used to inform the development of a planned Notice of Proposed Rulemaking, which is anticipated to be published in the spring of 2019.

Dated: October 25, 2018.

Lynn A. Johnson,

Assistant Secretary for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3442]

Agency Information Collection Activities; Proposed Collection; Comment Request; Web-Based Pilot Survey To Assess Allergy to Cosmetics in the United States

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a pilot study entitled “Web-based Pilot Survey to Assess Allergy to Cosmetics in the United States.”

DATES: Submit either electronic or written comments on the collection of information by January 7, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 7, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time

at the end of January 7, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2018-N-3442 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Web-based Pilot Survey to Assess Allergy to Cosmetics in the United States.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9

a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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, PRStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the 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. “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.