

assistance activities delivered to health centers to improve their capacity to recruit, develop, and retain their workforce to address national health care workforce shortages.

**FOR FURTHER INFORMATION CONTACT:**

Tracey Orloff, Strategic Partnerships Division Director in the Office of Quality Improvement, at [TOrloff@hrsa.gov](mailto:TOrloff@hrsa.gov) or 301.443.3197.

**SUPPLEMENTARY INFORMATION:**

*Intended Recipient of the Award:* Association of Clinicians for the Underserved, Inc.

*Amount of Non-Competitive Award:* \$275,000.

*Period of Supplemental Funding:* August 2021 to June 2023.

ALN: 93.129.

*Authority:* Section 330(l) of the Public Health Service Act, 42 U.S.C. 254b(l).

*Justification:* The National Center for Health Workforce Analysis estimates a shortage of over 23,000 primary care physician positions by 2025. Recruitment and retention programs are needed for health centers to address health care workforce shortages, which limit their ability to deliver comprehensive, culturally competent, high quality primary health care services.

ACU has unique experience developing learning collaboratives and can leverage their Solutions, Training, and Assistance for Recruitment and Retention Center and the Health Center Recruitment & Retention Data Profile Dashboard to advance in-scope training and technical assistance activities focused on enhancing health centers' ability to recruit, retain, and upskill their workforce. Supplemental funding is critical to ensure the timely expansion of the Solutions, Training, and Assistance for Recruitment and Retention Center and dashboard activities that enable health centers to conduct workforce data analysis, develop strategic plans, and enhance recruitment processes to attract and retain providers. ACU has the organizational capacity, expertise, and partnerships with Primary Care Associations, Health Center Controlled Networks, and other National Training and Technical Assistance Partners in place to immediately disseminate resources, tools, and strategies to improve workforce shortages at health centers.

**Diana Espinosa,**

*Acting Administrator.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**4-in-1 Grant Program**

*Announcement Type:* New and Competing Continuation.

*Funding Announcement Number:* HHS-2022-IHS-UIHP2-0001.

*Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number:* 93.193.

**Key Dates**

*Application Deadline Date:* February 8, 2022.

*Earliest Anticipated Start Date:* March 25, 2022.

**I. Funding Opportunity Description**

*Statutory Authority*

The Indian Health Service (IHS) is accepting applications for grants for the 4-in-1 Grant Program. This program is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); and Title V of the Indian Health Care Improvement Act (IHCIA), at 25 U.S.C. 1653(c)-(e) (authorizing grants for Health Promotion and Disease Prevention (HP/DP) services, Immunization services, and Mental Health services), and 1660a (authorizing grants for Alcohol and Substance Abuse related services). This program is described in the Assistance Listings located at <https://sam.gov/content/home> (formerly known as Catalog of Federal Domestic Assistance) under 93.193.

*Background*

In the late 1960s, Urban Indian community leaders began advocating at the local, state, and Federal levels to address the unmet health care needs of Urban Indians, and requested health care services and programs. These efforts resulted in an increase of preventative, medical, and behavioral health services, but there was growing recognition of challenges preventing Urban Indians in seeking health care services. To address these barriers, advocacy focused on the development of culturally-appropriate activities that were unique to the social, cultural, and spiritual needs of American Indians and Alaska Natives residing in urban settings. Programs developed at that time were staffed by volunteers in storefront settings, with limited budgets, offering primary care and outreach and referral services.

In response to efforts of the Urban Indian community leaders, Congress appropriated funds in 1966 through the IHS for a pilot urban clinic in Rapid

City, South Dakota. In 1973, Congress appropriated funds to study unmet Urban Indian health needs in Minneapolis, Minnesota. The findings of this study documented cultural, economic, and access barriers to health care and led to congressional appropriations to support emerging Urban Indian clinics in several Bureau of Indian Affairs relocation cities, e.g., Seattle, San Francisco, Tulsa, and Dallas. In 1976, Congress passed the IHCIA establishing the Urban Indian health program, and reauthorized the IHCIA in 2010 to improve the health and well-being of all American Indians and Alaska Natives, including Urban Indians. The development of programs for Urban Indians residing in urban areas include HP/DP services, immunization services, alcohol and substance abuse related services, and mental health services, hereafter referred to as the "4-in-1 health program."

*Purpose*

The purpose of this program is to ensure the highest possible health status for Urban Indians. Funding will be used to support the 4-in-1 health program objectives. These programs are integral components of the IHS health care delivery system. Funds from this effort will ensure that comprehensive, culturally acceptable personal and public health services are available and accessible to Urban Indians.

*Required, Optional, and Allowable Activities*

Each grantee shall provide health care services under this award only to eligible Urban Indians living within the urban center in which the Urban Indian Organization (UIO) is situated. An "Urban Indian" eligible for services, as codified at 25 U.S.C. 1603(13), (27), and (28), includes any individual who:

1. Resides in an urban center, which is any community that has a sufficient Urban Indian population with unmet health needs to warrant assistance under the IHCIA, as determined by the Secretary, Health and Human Services (HHS), and who meets one or more of the following criteria:
  - a. Irrespective of whether he or she lives on or near a reservation, is a member of a Tribe, band, or other organized group of Indians, including:
    - i. Those Tribes, bands, or groups terminated since 1940, and
    - ii. those recognized now or in the future by the state in which they reside, or
  - b. Is a descendant, in the first or second degree, of any such member described in 1.a.; or

- c. Is an Eskimo, or Aleut, or other Alaska Native; or
- d. Is a California Indian;<sup>1</sup> or
- e. Is considered by the Secretary of the Department of the Interior to be an Indian for any purpose; or
- f. Is determined to be an Indian under regulations pertaining to Urban Indian health that are promulgated by the Secretary, HHS.

Each grantee is responsible for taking reasonable steps to confirm that the individual is eligible for IHS services as an Urban Indian.

## II. Award Information

### Funding Instrument—Grant

#### Estimated Funds Available

The total funding identified for fiscal year (FY) 2022 is approximately \$8.5 million. Individual award amounts for the first budget year are anticipated to be between \$160,000 and \$650,000. New applicants may apply for funding up to \$200,000; current 4-in-1 grantees may apply for funding up to the amount approved in the last noncompeting award and must demonstrate that they have complied with previous terms and conditions of their award. The funding available for competing and subsequent continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

#### Anticipated Number of Awards

Approximately 33 awards will be issued under this program announcement.

#### Period of Performance

The period of performance is for 5 years.

## III. Eligibility Information

### 1. Eligibility

- To be eligible for this FY 2022 funding opportunity, an applicant must be an Urban Indian organization, as defined by 25 U.S.C. 1603(29), that is currently administering a contract or receiving a grant pursuant to 25 U.S.C. 1653. The term “Urban Indian

<sup>1</sup> Consistent with 25 U.S.C. 1603(3), (13), (28), and 1679, eligibility of California Indians may be demonstrated by documentation that the individual:

1. Is a descendant of an Indian who was residing in the State of California on June 1, 1852;
2. Holds trust interests in public domain, national forest, or Indian reservation allotments; or
3. Is listed on the plans for distribution of assets of California Rancherias and reservations under the Act of August 18, 1958 (72 Stat. 619), or is the descendant of such an individual.

organization” means a nonprofit corporate body situated in an urban center, governed by an Urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in 25 U.S.C. 1653(a). Applicants must provide proof of nonprofit status with the application, e.g., 501(c)(3).

The program office will notify any applicants deemed ineligible.

**Note:** Please refer to Section IV.2 (Application and Submission Information/ Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as proof of nonprofit status.

### 2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

### 3. Other Requirements

Applications with budget requests that exceed the highest dollar amount outlined under Section II Award Information, Estimated Funds Available, or exceed the period of performance outlined under Section II Award Information, Period of Performance, are considered not responsive and will not be reviewed. The Division of Grants Management (DGM) will notify the applicant.

### Additional Required Documentation

#### Documentation of Support

The UIO must submit a letter of support from their organization’s board of directors.

#### Proof of Nonprofit Status

Organizations claiming nonprofit status must submit a current copy of the 501(c)(3) Certificate with the application.

## IV. Application and Submission Information

### 1. Obtaining Application Materials

The application package and detailed instructions for this announcement are available at <https://www.Grants.gov>.

Please direct questions regarding the application process to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

### 2. Content and Form Application Submission

Mandatory documents for all applicants include:

- Abstract (one page) summarizing the project.

- Application forms:

1. SF–424, Application for Federal Assistance.
2. SF–424A, Budget Information—Non-Construction Programs. Each of the 4-in-1 health program areas (HP/DP, immunization, alcohol and substance abuse, and mental health), should be addressed in a separate Grant Program Function or Activity row/column of the SF–424A.

3. SF–424B, Assurances—Non-Construction Programs.

- Project Narrative (not to exceed 20 pages). See Section IV.2.A, Project Narrative for instructions.

1. Background information on the organization.

2. Statement of need, proposed scope of work, required objectives, and activities that provide a description of what the applicant plans to accomplish and evaluation and performance measurement plan.

- Budget Justification and Narrative (not to exceed five pages). See Section IV.2.B, Budget Narrative for instructions.

- Letter of Support from the UIO’s Board of Directors.

- 501(c)(3) Certificate.

- Biographical sketches for all Key Personnel (not to exceed one page each).

- Contractor/Consultant proposed scope of work and letter of commitment (not to exceed one page each, if applicable).

- Disclosure of Lobbying Activities (SF–LLL), if applicant conducts reportable lobbying.

- Certification Regarding Lobbying (GG–Lobbying Form).

- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).

- Organizational Chart or written information that shows where the 4-in-1 health program areas fit into the larger organization.

- Documentation of current Office of Management and Budget (OMB) Financial Audit (if applicable).

Acceptable forms of documentation include:

1. Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or

2. Face sheets from audit reports.

Applicants can find these on the FAC website at <https://harvester.census.gov/facdissem/Main.aspx>.

### Public Policy Requirements

All Federal public policies apply to IHS grants and cooperative agreements. Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by

Federal law to individuals eligible for benefits and services from the IHS. See <https://www.hhs.gov/grants/grants/grants-policies-regulations/index.html>.

#### Requirements for Project and Budget Narratives

##### A. Project Narrative

This narrative should be a separate document that is no more than 20 pages and must: (1) Have consecutively numbered pages; (2) use black font 12 points or larger; (3) be single-spaced; and (4) be formatted to fit standard letter paper (8½ x 11 inches).

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation Criteria) and place all responses and required information in the correct section noted below or they will not be considered or scored. If the narrative exceeds the page limit, the application will be considered not responsive and will not be reviewed. The 20-page limit for the narrative does not include the standard forms, budget, budget justification, narrative, and/or other items.

There are three parts to the narrative: Part 1—Program Information; Part 2—Program Planning and Evaluation; and Part 3—Organizational Capacity. See below for additional details about what must be included in the narrative.

##### Part 1: Program Information

###### Section 1: Needs

The statement of need describes the history and urban center currently served by the applicant. The statement of need also provides the facts and evidence that support the need for each of the 4-in-1 health program areas and establishes that the UIO understands the problems and can reasonably address them.

- Describe the current service gaps, including disconnection between available services and unmet needs of Urban Indians. This should include services at the UIO and in communities where Urban Indians reside.

- Describe the need for an enhanced infrastructure to increase the capacity to implement, sustain, and improve effective health care services offered to Urban Indians and any other service gaps and problems related to the need for infrastructure development within the UIO.

##### Part 2: Program Planning and Evaluation

###### Section 1: Program Plans

State the purpose, goals, and objectives of your proposed projects. Clearly state how proposed activities address the needs detailed in the

statement of need. Describe fully and clearly plans to meet each of the 4-in-1 health program areas of this funding announcement. Each objective should be addressed with a corresponding time frame. Provide a work plan for year 1 budget period that details expected key activities, accomplishments, and includes responsible staff for each of the 4-in-1 health program areas.

###### Section 2: Program Evaluation

This section of the narrative should describe efforts to collect and report project data that will support and demonstrate grant activities for each of the 4-in-1 health program areas. Grantees will be required to participate in a national evaluation of the 4-in-1 grant program. Grantees will also be required to collect and report data pertaining to activities, processes, and outcomes. Data collection activities should capture and document actions conducted throughout awarded years, including activities that will contribute to relevant project impact. This section should also describe the applicant's plan to evaluate program activities, including any practice-based and evidence-based prevention or treatment programs implemented. The evaluation plan should describe expected results and any identified metrics to support program effectiveness. Evaluation plans should incorporate questions related to outcomes and processes, including documentation of lessons learned.

- Describe in a brief narrative a plan to monitor activities under each of the 4-in-1 health program areas to demonstrate progress towards program outcomes and inform future program decisions over the 5-year project period.

- Describe proposed evaluation methods, including performance measures and other data relevant to evaluation outcomes, including intended results (e.g., impact and outcomes). Include any partners who will assist in evaluation efforts if separate from the primary applicant.

##### Part 3: Organizational Capacity

*Section 1:* This section should describe your organizational capacity for each of the 4-in-1 health program areas. Current staff and future positions for the four program components should also be outlined.

- Identify qualified professionals who will implement and administer the proposed grant activities, including progress and financial reports.

- Identify a contact person to maintain open and consistent communication with the IHS program official on any programmatic barriers to meeting the requirements of the award.

- Describe the organization's current system and ability to develop partnerships with service providers and community programs, including families and support systems of Urban Indians.

- Describe potential project partners and community resources in the urban center.

##### B. Budget Narrative (Limit—5 Pages)

Provide a budget narrative that explains the amounts requested for each line item of the budget from the SF-424A (Budget Information for Non-Construction Programs). The budget narrative document can include a more detailed spreadsheet than is provided by the SF-424A. Each 4-in-1 health program area should have a separate budget. The budget narrative should specifically describe how each item will support the achievement of proposed objectives. Be very careful about showing how each item in the "Other" category is justified. For subsequent budget years (see Multi-Year Project Requirements in Section V.1, Application Review Information, Evaluation Criteria), the narrative should highlight the changes from the first year or clearly indicate that there are no substantive budget changes during the period of performance. Do NOT use the budget narrative to expand the project narrative.

##### 3. Submission Dates and Times

Applications must be submitted through *Grants.gov* by 11:59 p.m. Eastern Time on the Application Deadline Date. Any application received after the application deadline will not be accepted for review. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the application process, contact *Grants.gov* Customer Support (see contact information at <https://www.Grants.gov>). If problems persist, contact Mr. Paul Gettys ([Paul.Gettys@ihs.gov](mailto:Paul.Gettys@ihs.gov)), Acting Director, DGM, by telephone at (301) 443-2114 or (301) 443-5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

The IHS will not acknowledge receipt of applications.

##### 4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

### 5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and indirect costs.
- Only one grant may be awarded per applicant.

### 6. Electronic Submission Requirements

All applications must be submitted via *Grants.gov*. Please use the <https://www.Grants.gov> website to submit an application. Find the application by selecting the “Search Grants” link on the homepage. Follow the instructions for submitting an application under the Package tab. No other method of application submission is acceptable.

If the applicant cannot submit an application through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Paul Gettys, Acting Director, DGM. A written waiver request must be sent to [GrantsPolicy@ihs.gov](mailto:GrantsPolicy@ihs.gov) with a copy to [Paul.Gettys@ihs.gov](mailto:Paul.Gettys@ihs.gov). The waiver request must: (1) Be documented in writing (emails are acceptable) before submitting an application by some other method; and (2) include clear justification for the need to deviate from the required application submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions. A copy of the written approval must be included with the application that is submitted to the DGM. Applications that are submitted without a copy of the signed waiver from the Acting Director of the DGM will not be reviewed. The Grants Management Officer of the DGM will notify the applicant via email of this decision. Applications submitted under waiver must be received by the DGM no later than 5:00 p.m. Eastern Time on the Application Deadline Date. Late applications will not be accepted for processing. Applicants that do not register for both the System for Award Management (SAM) and *Grants.gov* and/or fail to request timely assistance with technical issues will not be considered for a waiver to submit an application via alternative method.

Please be aware of the following:

- Please search for the application package in <https://www.Grants.gov> by entering the Assistance Listing (CFDA) number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application, please contact *Grants.gov* Customer Support (see contact information at <https://www.Grants.gov>).

• Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.

• Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to 20 working days.

• Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by this funding announcement.

• Applicants must comply with any page limits described in this funding announcement.

• After submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The IHS will not notify the applicant that the application has been received.

### Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

Applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B that uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access the request service through <https://fedgov.dnb.com/webform>, or call (866) 705-5711.

The Federal Funding Accountability and Transparency Act of 2006, as amended (“Transparency Act”), requires all HHS recipients to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

### System for Award Management (SAM)

Organizations that are not registered with SAM must have a DUNS number first, then access the SAM online registration through the SAM home page at <https://sam.gov> (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active).

Please see *SAM.gov* for details on the registration process and timeline. Registration with the SAM is free of charge but can take several weeks to process. Applicants may register online at <https://sam.gov>.

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, are available on the DGM Grants Management, Policy Topics web page at <https://www.ihs.gov/dgm/policytopics/>.

### V. Application Review Information

Possible points assigned to each section are noted in parentheses. The project narrative and budget narrative should include only the first year of activities; information for multi-year projects should be included as a separate document. See “Multi-year Project Requirements” at the end of this section for more information. The project narrative should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to fully understand the project. Attachments requested in the criteria do not count toward the page limit for the project narrative. Points will be assigned to each evaluation criteria adding up to a total of 100 possible points. Points are assigned as follows:

#### 1. Evaluation Criteria

Applications will be reviewed and scored according to the quality of responses to the required application components in Sections A–E outlined below. In developing the required sections of this application, use the instructions provided for each section, which have been tailored to this program. The application must use the five sections (Sections A–E) listed below in developing the narratives. The applicant must place the required information in the correct section or it will not be considered for review. The application will be scored according to how well the applicant addresses the requirements for each section listed below. The number of points after each section heading is the maximum number of points the Objective Review Committee (ORC) may assign to that section. Although scoring weights are not assigned to individual bullets, each bullet is assessed deriving the overall section score.

#### A. Introduction and Need for Assistance (25 Points)

1. Identify the proposed urban center and provide demographic information

on the population(s) to receive services. Describe the stakeholders and resources in the urban center that can help implement activities for each of the 4-in-1 health program areas.

2. Based on the information and/or data currently available, document the need to implement, sustain, and improve health care services offered to Urban Indians.

3. Based on available data, describe the service gaps and other problems related to the needs of Urban Indians. Identify the source of the data.

Documentation of need may come from a variety of qualitative and quantitative sources. Examples of data sources for the quantitative data that could be used are local epidemiologic data such as Tribal Epidemiology Centers or IHS Area Offices, state data from state needs assessments, and/or national data from the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Survey on Drug Use and Health, or from the National Center for Health Statistics/Centers for Disease Control, and U.S. Census data (American Community Survey, etc.). This list is not exhaustive. Applicants may submit other valid data, as appropriate, for the applicant's programs.

#### B. Project Objective(s), Work Plan, and Approach (30 Points)

1. Describe the purpose of the proposed project, including a clear statement of goals and objectives. The project narrative is required to address each of the 4-in-1 health program areas.

a. *HP/DP*: Applicants are encouraged to use evidence-based and promising strategies that can be found at the IHS best practice database at <https://www.ihs.gov/hpdp/>, SAMHSA Evidence-based Practices Resource Center at <https://www.samhsa.gov/resource-search/ebp>, and the Guide to Community Preventive Services at <https://www.thecommunityguide.org/about/about-community-guide>. Applicants are encouraged to work collaboratively with their assigned Area HP/DP Coordinator.

b. *Immunization*: Applicants are encouraged to participate in the Vaccines for Children program (if applicable). Applicants are encouraged to research capability with state/regional immunization registry (where applicable). For sites using the IHS Resource and Patient Measurement System (RPMS), provide training sessions to providers and data entry clerks on the RPMS Immunization package. Establish a process for immunization data entry into RPMS (e.g., point of service or through

standard data entry). Utilize the RPMS Immunization package to identify 3- to 27-month-old children whose immunization records are not up to date and that generate reminder/recall letters. Applicants are encouraged to work collaboratively with their assigned Area Immunization Coordinator.

c. *Alcohol and Substance Abuse*: Describe services to be provided, e.g., residential, detox, halfway house, counseling, outreach and referral, etc. Describe substance abuse prevention and education efforts to increase access to services, outreach, education, prevention, and treatment of substance abuse related issues. Applicants are encouraged to work collaboratively with their assigned Area Behavioral Health Consultant.

d. *Mental Health*: Identify services to be provided, e.g., community outreach and referral, prevention, training sessions, evaluations, schools, domestic violence programs, child abuse programs, etc. Describe mental health prevention and education program efforts to increase access to services, outreach, referral, education, prevention, and treatment of mental health related issues. Applicants are encouraged to work collaboratively with their assigned Area Behavioral Health Consultant.

2. Describe how project activities will increase the capacity of the UIO to improve access to and quality of care for Urban Indians.

3. Describe anticipated barriers and how these barriers will be addressed.

4. Describe how the proposed project will address issues of diversity for Urban Indians, including race/ethnicity, gender, culture/cultural identity, language, sexual orientation, disability, and literacy.

5. Describe how Urban Indians may receive services for the 4-in-1 health program areas and how they will be involved in the planning and implementation of the grant.

6. Describe how the efforts of the proposed project will be coordinated with any other related Federal grants, including the IHS, Centers for Disease Control and Prevention, SAMHSA, or Health Resources and Services Administration, etc. (if applicable).

7. Provide a work plan for the first year budget period that details expected key activities, accomplishments, and includes responsible staff for each of the 4-in-1 health program areas.

#### C. Program Evaluation (20 Points)

Describe plans to monitor activities under each of the 4-in-1 health program areas, demonstrate progress towards program outcomes, and inform future

program decisions over the 5 year project period. Applications should address the following points:

1. Describe proposed data collection efforts (performance measures and associated data) and how you will use the data to answer evaluation questions. This should include data collection method, data source, data measurement tool, identified staff for data management, and data collection timeline.

2. Identify key program partners and describe how they will participate in the implementation of the evaluation plan (e.g., Tribal Epidemiology Centers, universities, etc.).

3. Describe data collection and evaluation of any proposed practice-based and/or evidence-based care programs implemented throughout awarded years.

4. Describe how evaluation findings will be used at the applicant level. Discuss how data collected (e.g., performance measurement data) will be used and shared by the key program partners.

5. Discuss any barriers or challenges expected for implementing the plan, collecting data (e.g., responding to performance measures), and reporting on evaluation results. Describe how these potential barriers would be overcome. In addition, applicants may also describe other measures to be developed or additional data sources and data collection methods that applicants will use.

#### D. Organizational Capabilities, Key Personnel, and Qualifications (15 Points)

1. Describe the management capability of the UIO and other participating organizations in administering similar projects.

2. Identify staff to maintain open and consistent communication with the IHS program official on any financial or programmatic barriers to meeting the requirements of the award.

3. Identify the department(s) and/or division(s) that will administer each of the 4-in-1 health program areas. Include a description of these department(s) and/or division(s), their functions, and their placement within the UIO and their direct link to management.

4. Discuss the UIO's experience and capacity to provide culturally appropriate and competent services to the community and specific populations of focus.

5. Describe the resources available for the proposed project (e.g., facilities, equipment, information technology systems, and financial management systems).

6. Identify other organization(s) that will participate in the proposed project. Describe their roles and responsibilities and demonstrate their commitment to each of the 4-in-1 health program areas.

7. Describe how project continuity will be maintained if there is a change in the operational environment (*e.g.*, staff turnover, change in project leadership, etc.) to ensure project stability over the life of the grant.

8. Provide a list of staff positions for the project and other key personnel, showing the role of each and their level of effort and qualifications for each of the 4-in-1 health program areas. Key personnel include the Chief Executive Officer or Executive Director, Chief Financial Officer, Medical Director, and Chief Information Officer.

9. Demonstrate successful project implementation for the level of effort budgeted for the project staff and other key staff.

10. Include position descriptions (upload as Other Attachments) for all key personnel. Position descriptions should not exceed one page each. Reviewers will not consider information past one page.

11. For individuals who are currently on staff, include a biographical sketch with their name (do not include personally identifiable information such as social security number or date and place of birth) for each individual that will be listed as the project staff and other key positions. Describe the experience of identified staff in each of the 4-in-1 health program areas. Upload each biographical sketch in the Other Attachments form in your *Grants.gov* application workspace. Biographical sketches should not exceed one page per staff member. Reviewers will not consider information past one page. Do not include any of the following:

- a. Personally Identifiable Information (social security number and date and place of birth);
- b. Resumes; or
- c. Curriculum Vitae.

#### E. Categorical Budget and Budget Justification (10 Points)

1. Include a line item budget for each of the 4-in-1 health program areas for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative for the first budget year only.

2. Provide a categorized budget for each of the 4-in-1 health program areas.

3. Applicants should ensure that the budget and budget narrative are aligned with the project narrative. The budget and budget narrative the applicant provides will be considered by

reviewers in assessing the applicant's submission, along with the material in the project narrative. Questions to address include: What resources are needed to successfully carry out and manage the project? What other resources are available from the organization? Will new staff be recruited? Will outside consultants be required?

4. For any outside consultants, include the total cost broken down by activity.

5. If indirect costs are claimed, indicate and apply the current negotiated rate to the budget. Include a copy of the current negotiated IDC rate agreement in the Other Attachments form in the application workspace.

#### Multi-Year Project Requirements

Applications must include a brief project narrative and budget (1 additional page per year) addressing the developmental plans for each additional year of the project. This attachment will not count as part of the project narrative or the budget narrative.

Additional documents can be uploaded as Other Attachments in *Grants.gov*. These can include:

- Work plan, logic model, and/or timeline for proposed objectives.
- Position descriptions for key staff (not to exceed one page each).
- Biographical sketch of key staff that reflect current duties (not to exceed one page each).
- Consultant or contractor proposed scope of work and letter of commitment (not to exceed one page each) (if applicable).
- Current Indirect Cost Rate Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.*, data tables, key news articles, etc.).

#### 2. Review and Selection

Each application will be prescreened for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria. Incomplete applications and applications that are not responsive to the administrative thresholds (budget limit, project period limit) will not be referred to the ORC and will not be funded. The applicant will be notified of this determination. Applicants must address all program requirements and provide all required documentation.

#### 3. Notifications of Disposition

All applicants will receive an Executive Summary Statement from the IHS Office of Urban Indian Health Programs within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorizing Official identified on the face page (SF-424) of the application.

#### A. Award Notices for Funded Applications

The Notice of Award (NoA) is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period. Each entity approved for funding must have a user account in GrantSolutions in order to retrieve the NoA. Please see the Agency Contacts list in Section VII for the systems contact information.

#### B. Approved but Unfunded Applications

Approved applications not funded due to lack of available funds will be held for 1 year. If funding becomes available during the course of the year, the application may be reconsidered.

**Note:** Any correspondence, other than the official NoA executed by an IHS grants management official announcing to the project director that an award has been made to their organization, is not an authorization to implement their program on behalf of the IHS.

## VI. Award Administration Information

### 1. Administrative Requirements

Awards issued under this announcement are subject to, and are administered in accordance with, the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards currently in effect or implemented during the period of award, other Department regulations and policies in effect at the time of award, and applicable statutory provisions. At the time of publication, this includes 45 CFR part 75, at <https://www.govinfo.gov/content/pkg/CFR-2020-title45-vol1/pdf/CFR-2020-title45-vol1-part75.pdf>.

• Please review all HHS regulatory provisions for Termination at 45 CFR 75.372, at <https://www.ecfr.gov/cgi-bin/>

*retrieveECFR?gp&SID=2970eec67399fab1413ede53d7895d99&mc=true&n=pt45.1.75&r=PART&ty=HTML&se45.1.75\_1372#se45.1.75\_1372.*

#### C. Grants Policy:

- HHS Grants Policy Statement, Revised January 2007, at <https://www.hhs.gov/sites/default/files/grants/policies/policies-regulations/hhsgps107.pdf>.

#### D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, “Cost Principles,” located at 45 CFR part 75 subpart E.

#### E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, “Audit Requirements,” located at 45 CFR part 75 subpart F.

F. As of August 13, 2020, 2 CFR 200 was updated to include a prohibition on certain telecommunications and video surveillance services or equipment. This prohibition is described in 2 CFR 200.216. This will also be described in the terms and conditions of every IHS grant and cooperative agreement awarded on or after August 13, 2020.

## 2. Indirect Costs

This section applies to all recipients that request reimbursement of indirect costs (IDC) in their application budget. In accordance with HHS Grants Policy Statement, Part II–27, the IHS requires applicants to obtain a current IDC rate agreement and submit it to the DGM prior to the DGM issuing an award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award’s budget period. If the current rate agreement is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate agreement is provided to the DGM.

Per 45 CFR 75.414(f) Indirect (F&A) costs, “any non-Federal entity (NFE) [i.e., applicant] that has never received a negotiated indirect cost rate, . . . may elect to charge a de minimis rate of 10 percent of modified total direct costs which may be used indefinitely. As described in Section 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as the NFE chooses to

negotiate for a rate, which the NFE may apply to do at any time.”

Electing to charge a de minimis rate of 10 percent only applies to applicants that have never received an approved negotiated indirect cost rate from HHS or another cognizant federal agency. Applicants awaiting approval of their indirect cost proposal may request the 10 percent de minimis rate. When the applicant chooses this method, costs included in the indirect cost pool must not be charged as direct costs to the grant.

Available funds are inclusive of direct and appropriate indirect costs. Approved indirect funds are awarded as part of the award amount, and no additional funds will be provided.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation at <https://rates.psc.gov/> or the Department of the Interior (Interior Business Center) at <https://ibc.doi.gov/ICS/tribal>. For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under “Agency Contacts” or the main DGM office at (301) 443–5204.

### 3. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in the imposition of special award provisions and/or the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the awardee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports must be submitted electronically by attaching them as a “Grant Note” in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in Section VII for the systems contact information.

The reporting requirements for this program are noted below.

#### A. Progress Reports

Program progress reports are required quarterly. The progress reports are due within 30 days after the reporting period ends (specific dates will be listed in the NoA Terms and Conditions). Grantees have the option to use the 4-in-1 Grant

Reporting Template instead of developing their own format. The template is available at the 4-in-1 Grant web page at <https://www.ihs.gov/urban/4-in-1-grant-program/>.

The quarterly Progress Report shall demonstrate actual goals and objectives were met against established target measures, a summation of the program approach, and report on integrated cultural interventions and implementation of practice-based and/or evidence-based approaches, including a concise summary narrative of the program’s impact on the Urban Indian service population. If applicable, program changes for the next reporting period may be included.

To comply with statutory requirements consistent with 25 U.S.C. 1653(a), 1655, and 1657(a), the Progress Reporting Template includes a section for the grantee to report their unmet needs or the grantee may use their own format to report their unmet needs. This includes information gathered by the grantee to: (1) Identify gaps between unmet health needs of Urban Indians and the resources available to meet such needs; and (2) make recommendations to the Secretary and Federal, state, local, and other resource agencies on methods of improving health services to meet the needs of Urban Indians.

The final end of year and 4th quarter report must be submitted within 90 days of expiration of the period of performance.

#### B. Financial Reports

Federal Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services at <https://pms.psc.gov>. Failure to submit timely reports may result in adverse award actions blocking access to funds.

Federal Financial Reports are due 30 days after the end of each budget period, and a final report is due 90 days after the end of the Period of Performance. Grantees are responsible and accountable for reporting accurate information on all required reports: The Progress Reports, the Federal Cash Transaction Report, and the Federal Financial Report.

#### C. Data Collection and Reporting

##### 1. Government Performance and Results Act Reporting (GPRA)

The GPRA data period shall be the Federal fiscal year of October 1 through September 30. GPRA data shall be submitted electronically to the National Data Warehouse (NDW). All GPRA data submitted shall be verifiable and based upon criteria set forth for each GPRA

performance standard. Monthly registration and workload data shall be exported to the NDW. All data shall be exported by the cutoff date for that fiscal year. A GPRA Developmental Report shall be run at the end of the second and fourth quarters and sent to the National GPRA Support Team at [caogpra@ihs.gov](mailto:caogpra@ihs.gov) by the required due dates.

## 2. Uniform Data System (UDS)

UDS reporting period shall be by calendar year. The UDS reports shall be due in January for the previous calendar year.

## 3. Quarterly Immunization Report

Quarterly Immunization Reports are required and submitted to the online National Immunization Reporting System (NIRS) (<https://www.ihs.gov/NonMedicalPrograms/ihpes/immunizations/index.cfm?module=immunizations&option=home>). Grantees are required to submit immunization coverage reports on children 3 to 27-month-old, 2-year-old, Adolescent, Adult, and Influenza on a quarterly basis. For sites not using the IHS RPMS, visit the Division of Epidemiology and Disease Prevention (DEDP), Vaccine-Preventable Diseases Reports website to access non-RPMS quarterly reporting forms. An Excel spreadsheet with the required data elements can be found under the "Non-RPMS Quarterly Reporting Forms" section at <https://www.ihs.gov/epi/vaccine/reports/>.

## D. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards. The IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs, and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a \$25,000 sub-award obligation threshold met for any specific reporting period.

For the full IHS award term implementing this requirement and additional award applicability

information, visit the DGM Grants Management website at <https://www.ihs.gov/dgm/policytopics/>.

## E. Compliance With Executive Order 13166 Implementation of Services Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Should you successfully compete for an award, recipients of Federal financial assistance (FFA) from HHS must administer their programs in compliance with Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html>.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficiency individuals, see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov>.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see <https://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.

- HHS funded health and education programs must be administered in an environment free of sexual harassment, see <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>.

- For guidance on administering your program in compliance with applicable Federal religious nondiscrimination laws and applicable Federal conscience protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

## F. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the FAPIIS at <https://www.fapiis.gov> before making any award in excess of the simplified acquisition threshold (currently \$250,000) over the period of performance. An applicant may review and comment on any information about itself that a Federal awarding agency previously entered. The IHS will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, NFEs are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive Federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than \$10,000,000 for any period of time during the period of performance of an award/project.

## Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, the IHS must require an NFE or an applicant for a Federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award.

All applicants and recipients must disclose in writing, in a timely manner, to the IHS and to the HHS Office of Inspector General all information related to violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. 45 CFR 75.113.

Disclosures must be sent in writing to: U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Paul Gettys, Acting Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, (Include "Mandatory Grant Disclosures" in subject line), Office: (301) 443-5204, Fax: (301) 594-0899, Email: [Paul.Gettys@ihs.gov](mailto:Paul.Gettys@ihs.gov).  
AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW, Cohen Building, Room 5527, Washington, DC 20201, URL: <https://oig.hhs.gov/fraud/report-fraud/>, (Include “Mandatory Grant Disclosures” in subject line), Fax: (202) 205-0604 (Include “Mandatory Grant Disclosures” in subject line) or Email: [MandatoryGranteeDisclosures@oig.hhs.gov](mailto:MandatoryGranteeDisclosures@oig.hhs.gov).

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (see 2 CFR part 180 and 2 CFR part 376).

## VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Debi Nalwood, Health System Specialist, Indian Health Service, Office of Urban Indian Health Programs, 5600 Fishers Lane, Mail Stop: 08E65D, Rockville, MD 20857, Phone: (240) 701-0882, Email: [Debi Allison.Nalwood@ihs.gov](mailto:Debi Allison.Nalwood@ihs.gov).

2. Questions on grants management and fiscal matters may be directed to: Pallop Chareonvootitam, Grants Management Specialist, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2195, Email: [Pallop.Chareonvootitam@ihs.gov](mailto:Pallop.Chareonvootitam@ihs.gov).

3. Questions on systems matters may be directed to: Paul Gettys, Acting Director, Division of Grants Management, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2114; or the DGM main line (301) 443-5204, Email: [Paul.Gettys@ihs.gov](mailto:Paul.Gettys@ihs.gov).

## VIII. Other Information

The Public Health Service strongly encourages all grant, cooperative agreement, and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to

protect and advance the physical and mental health of the American people.

**Elizabeth A. Fowler,**

*Acting Director, Indian Health Service.*

[FR Doc. 2021-24577 Filed 11-9-21; 8:45 am]

**BILLING CODE 4165-16-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel; RFA Review: Practice-Based Research for Implementing Scalable Evidence-Based Prevention Interventions in Primary Care Settings.

*Date:* December 3, 2021.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Nicholas Gaiano, Ph.D., Review Branch Chief, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center/Room 6150/MS-C9606, 6001 Executive Boulevard, Bethesda, MD 20892-9606, 301-443-2742, [nick.gaiano@nih.gov](mailto:nick.gaiano@nih.gov).

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: November 4, 2021.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2021-24517 Filed 11-9-21; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2021-0626]

#### Collection of Information Under Review by Office of Management and Budget; OMB Control Number 1625-0094

**AGENCY:** Coast Guard, DHS.

**ACTION:** Thirty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625-0094, Ships Carrying Bulk Hazardous Liquids; without change.

Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

**DATES:** You may submit comments to the Coast Guard and OIRA on or before December 10, 2021.

**ADDRESSES:** Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov>. Search for docket number [USCG-2021-0626]. Written comments and recommendations to OIRA for the proposed information collection should be sent within 30 days of publication of this notice to <https://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.

A copy of the ICR is available through the docket on the internet at <https://www.regulations.gov>. Additionally, copies are available from: Commandant (CG-6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, STOP 7710, Washington, DC 20593-7710.

**FOR FURTHER INFORMATION CONTACT:** A.L. Craig, Office of Privacy Management, telephone 202-475-3528, or fax 202-372-8405, for questions on these documents.

**SUPPLEMENTARY INFORMATION:**