request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. The proposal was received on March 23, 2015. Mr. Khan failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and has waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Talib Khan has been convicted of felonies under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing finding, Talib Khan is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see DATES)(see section 201(dd), 306(c)(1)(B), and 306(c)(2)(A)(ii) of the FD&C Act, (21 U.S.C. 321(dd), 335a(c)(1)(B), and 335a(c)(2)(A)(ii)). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Talib Khan, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Khan provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug applications from Talib Khan during his period of debarment (section 306(c)(1)(B) of the FD&C Act (21 U.S.C. 335a(c)(1)(B))).

Any application by Mr. Khan for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) should be identified with Docket No. FDA–2014–N–2103 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 25, 2015.

Douglas Stearn,

Director, Division of Compliance Policy, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2015–16664 Filed 7–7–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than August 7, 2015.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 594–4306.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Maternal, Infant, and Childhood Home Visiting (Home Visiting) Program Fiscal Year (FY) 2015, FY2016, FY2017 Non-Competing Continuation Annual Progress Report for Formula Grant.

OMB No.: 0915–0355—Extension.

Abstract: The Maternal, Infant, and Early Childhood Home Visiting (Home Visiting) Program, administered by the Health Resources and Services Administration (HRSA) in close partnership with the Administration for Children and Families (ACF), supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. The purpose of this formula grant program is to: support the delivery of coordinated and comprehensive voluntary early childhood home visiting program services and effective implementation of high-quality evidence-based practices. The fifty states, District of Columbia, and 5 territories and nonprofit organizations that would provide services in jurisdictions that have not directly applied for or been approved for a grant are eligible for formula grants and submit non-competing continuation progress reports annually. There are 56 jurisdictions eligible for formula awards and 56 formula awards are issued annually.

Need and Proposed Use of the Information: This information collection is needed for eligible entities to report progress under the Home Visiting Program annually. On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (ACA). Section 2951 of the ACA amended Title V of the Social Security Act by adding a new section, 511, which authorized the creation of the Home Visiting Program (*http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf,* pages 216–225). A portion of funding under this program is awarded to participating states and eligible jurisdictions by formula. The purpose of formula funding is to support the delivery of coordinated and comprehensive voluntary early childhood home visiting program services and effective implementation of high-quality evidence-based practices.

The information collected will be used to review grantee progress on proposed project plans sufficient to permit project officers to assess whether the project is performing adequately to achieve the goals and objectives that were previously approved. This report will also provide implementation plans for the upcoming year, which project officers can use to assess to whether the plan is consistent with the grant as approved, and will result in implementation of a high-quality project that will complement the home visiting program as a whole. Progress Reports are submitted to project officers through the Electronic HandBooks (EHB). Failure to collect this information would result in the inability of the project officers to exercise due diligence in monitoring and overseeing the use of grant funds in keeping with legislative, policy, and programmatic requirements. Grantees are required to provide a performance narrative with the following sections: project identifier

information, accomplishments and barriers, home visiting program goals and objectives, update on the home visiting program promising approach, implementation of the home visiting program in targeted at-risk communities, progress toward meeting legislatively-mandated reporting on benchmark areas, home visiting quality improvement efforts, and updates on the administration of the home visiting program.

In the event a new Funding Opportunity Announcement is issued annually for the formula grant program, the application for new grant funds may take the place of completion of a non-competing continuation progress report.

Likely Respondents: Grantees with Home Visiting Formula Awards Awarded in Federal FYs 2013—2017.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden—Hours: The burden estimates presented in the table below are based on consultations with a few states on the guidance. Grantees receive a new formula grant annually and are expected to report on progress annually, so the expectation is that grantees would submit non-competing continuation progress reports four times between federal fiscal years 2015 and 2018. Only seven grantees are currently implementing a promising approach and require an annual update on the promising approach.

Form name	Number of respondents	Number of responses per respondent	Total responses	Hours per response	Total burden hours
Formula Grant Award	56	4	224	42	9408
Total	56	4	224	42	9408

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–16697 Filed 7–7–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Clinical and Preventive Services; Division of Behavioral Health; Domestic Violence Prevention Initiative

Announcement Type: New —Limited Competition

Funding Announcement Number: HHS–2015–IHS–DVPI–0001

Catalog of Federal Domestic Assistance Number (CFDA): 93.933

Key Dates

Application Deadline Date: September 8, 2015

Review Date: September 14–18, 2015

Earliest Anticipated Start Date: September 30, 2015

Signed Tribal Resolutions Due Date: September 11, 2015

Proof of Non-Profit Status Due Date: September 8, 2015

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS), an agency which is part of the Department of Health and Human Services (HHS), is accepting applications for a five-year funding cycle, to continue the planning, development, and implementation of the Domestic Violence Prevention Initiative (Short Title: DVPI). This program was first established by the Omnibus Appropriations Act of 2009, Public Law 111–8, 123 Stat. 524, 735, and continued in the annual appropriations acts since that time. This program is authorized under the authority of 25 U.S.C. 13, the Snyder Act, and the Indian Health Care Improvement Act, 25 U.S.C. 1601–1683. The amounts made available for the DVPI shall be allocated at the discretion of the Director, IHS and shall remain available until expended. IHS utilizes a national funding formula developed in consultation with Tribes and the National Tribal Advisory Committee (NTAC) on behavioral health, as well as conferring with urban Indian health programs (UIHPs). The funding formula provides the allocation methodology for each IHS Service Area. This program is described in the Catalog of Federal Domestic Assistance under 93.933.

Background

From August 2010–August 2015, IHS funded 65 IHS, Tribal, Tribal organizations, and UIHPs that participated in a nationally coordinated five-year demonstration pilot project to expand outreach and increase awareness of domestic and sexual violence and provide victim advocacy, intervention, case coordination, policy development, community response teams, and community and school education programs. The DVPI promotes the development of evidence-based and practice-based models that represent culturally appropriate prevention and treatment approaches to domestic and sexual violence from a community-driven context. For a complete listing of demonstration pilot projects, please visit *www.ihs.gov/dvpi/pilotprojects.*

Purpose

The primary purpose of this grant program is to accomplish the DVPI goals listed below:

1. Build Tribal, UIHP, and Federal capacity to provide coordinated community responses to American Indian/Alaska Native (AI/AN) victims of domestic and sexual violence.

2. Increase access to domestic and sexual violence prevention, advocacy, crisis intervention, and behavioral health services for AI/AN victims and their families.

3. Promote trauma-informed services for AI/AN victims of domestic and sexual violence and their families.

4. Offer healthcare provider and community education on domestic and sexual violence.

5. Respond to the healthcare needs of AI/AN victims of domestic and sexual violence.

6. Incorporate culturally appropriate practices and/or faith-based services for AI/AN victims of domestic and sexual violence.

To accomplish the DVPI goals, IHS invites applicants to address one of the Purpose Areas below: