including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

513(g) Request for Information

OMB Control Number 0910–0705—Extension

Section 513(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(g)) provides a means for obtaining the Agency's views about the classification and regulatory requirements that may be applicable to a particular device. Section 513(g) provides that, within 60 days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act, the Secretary of Health and Human Services shall provide such person a written statement of the classification (if any) of such device and the requirements of the FD&C Act applicable to the device.

The guidance document entitled ''FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act; Guidance for Industry and Food and Drug Administration Staff'' establishes procedures for submitting, reviewing, and responding to requests for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act that are submitted in accordance with section 513(g) of the FD&C Act. FDA does not review data related to substantial equivalence or safety and effectiveness in a 513(g) request for information. FDA's responses to 513(g) requests for information are not device classification decisions and do not constitute FDA clearance or approval for marketing. Classification decisions and clearance or approval for marketing require submissions under different sections of the FD&C Act.

Additionally, the FD&C Act, as amended by the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), requires FDA to collect user fees for 513(g) requests for information. The guidance document entitled ''Guidance for Industry and Food and Drug Administration Staff; User Fees for 513(g) Requests for Information'' assists FDA staff and regulated industry by describing the user fees associated with 513(g) requests. The Medical Device User Fee Cover Sheet (Form FDA 3601), which accompanies the supplemental material described in this information collection is approved under OMB control number 0910–0511 and expires August 31, 2019.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDRH 513(g) requests	114	1	114	12	1,368
CBER 513(g) requests	4	1	4	12	48
Total					1,416

[1] There are no capital costs of operating and maintenance costs associated with this collection off information.

Respondents of this collection of information are mostly device manufacturers; however, anyone may submit a 513(g) request for information. The total number of annual responses is based on the average number of 513(g) requests received each year by the Agency.

Dated: November 9, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–25159 Filed 11–20–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Supplemental Award to the National Network for Oral Health Access

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: HRSA announces the award of a supplement in the amount of $250,000 for a HRSA-funded cooperative agreement awarded to the National Network for Oral Health Access (NNOHA). The supplement, awarded on September 25, 2017, will fund demonstration projects to increase the integration of oral health and primary care practice through the adoption of HRSA's core clinical oral health competencies for non-dental health care providers in Health Center (HC) settings, focusing on services for pregnant women and children.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: National Network for Oral Health Access.

Amount of Non-Competitive Awards: $250,000.

Budget Periods of Supplemental Funding: July 1, 2017, through June 30, 2018.

CFDA Number: 93.110.

Authority: Special Projects of Regional and National Significance program (Social Security Act, Title V, § 501(a)(2) (42 U.S.C. 701(a)(2)).

Justification: The National Network for Oral Health Access (NNOHA) supports goals to improve access to oral

health care, increase awareness of the connection between oral health and overall health, prevent disease and promote oral health, and improve health literacy to health providers and patients alike. HRSA developed a core set of oral health clinical competencies for non-dental providers as part of its Integration of Oral Health and Primary Care Practice (IOHPCP) initiative in response to recommendations from two Institute of Medicine (IOM) reports: *Advancing Oral Health in America* and *Improving Access to Oral Health Care for Vulnerable and Underserved Populations.* NNOHA participated in the IOHPCP initiative and in fiscal year (FY) 2012 received supplemental funding (U30CS09745–05–02) to implement a pilot project in safety net settings to inform the impact and effectiveness of oral health core clinical competencies and inter-professional collaboration in primary care settings. The goal of the project was to increase integration of oral health and primary health care. NNOHA published the pilot project results in a user guide entitled, *User's Guide for Implementation of inter-professional oral health core clinical competencies* and continues to provide technical assistance to health centers and training on oral health integration and primary care practice.

The Joint Explanatory Statement to the Consolidated Appropriations Act of FY 2017 encouraged HRSA to allocate $250,000 for demonstration projects to support the implementation of integrating oral health and primary care projects. The projects are to model the core clinical oral health competencies for non-dental providers that HRSA published and initially tested in its 2014 report, *Integration of Oral Health and Primary Care Practice.* In order to achieve this goal, HRSA will provide supplemental funding to the NNOHA to advance and expand the implementation of oral health core clinical competencies in health centers, focusing on services for pregnant women and children. Additionally, these demonstration projects will directly align with four HRSA recommendations for effectively incorporating the competencies into clinical practice as described in the 2014 *Integrating Oral Health and Primary Care Practice* report. This activity is consistent with the current work plan of NNOHA and includes providing training and technical assistance on IOHPCP. NNOHA's primary roles are to coordinate all activities at the planning, implementation, evaluation, and dissemination stages, as well as provide technical assistance and training to participating HCs. NNOHA shall select no fewer than six HCs, which it supports as part of the current HRSA-funded National Training and Technical Assistance Cooperative Agreement Program (U30CS29051). NNOHA will assure that each HC will propose, implement, and track data for an innovative inter-professional oral health project that measurably increases the adoption of the core clinical oral health competencies among non-dental providers in the delivery of care to pregnant women and children.

FOR FURTHER INFORMATION CONTACT: Chinyere Amaefule, Office of Quality Improvement, Division of Strategic Partnerships, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857, Phone: (301) 594–4417, Email: *Camaefule@hrsa.gov.*

Grantee/organization name	Grant No.	State	FY 2017 authorized funding level	FY 2017–2018 estimated supplemental amount
National Network of Oral Health Access	U30CS29051	CO	$500,000	$250,000

Dated: November 14, 2017.

George Sigounas,

Administrator.

[FR Doc. 2017–25191 Filed 11–20–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Federal Matching Shares for Medicaid, the Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2018 Through September 30, 2019

AGENCY: Office of the Secretary, DHHS.

ACTION: Notice.

DATES: The percentages listed in Table 1 will be effective for each of the four quarter-year periods beginning October 1, 2018 and ending September 30, 2019.

FOR FURTHER INFORMATION CONTACT: Caryn Marks or Rose Chu, Office of Health Policy, Office of the Assistant Secretary for Planning and Evaluation, Room 447D—Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, (202) 690–6870.

SUPPLEMENTARY INFORMATION: The Federal Medical Assistance Percentages (FMAP), Enhanced Federal Medical Assistance Percentages (eFMAP), and disaster-recovery FMAP adjustments for Fiscal Year 2019 have been calculated pursuant to the Social Security Act (the Act). These percentages will be effective from October 1, 2018 through September 30, 2019. This notice announces the calculated FMAP rates, in accordance with sections 1101(a)(8) and 1905(b) of the Act, that the U.S. Department of Health and Human Services (HHS) will use in determining the amount of federal matching for state medical assistance (Medicaid), Temporary Assistance for Needy Families (TANF) Contingency Funds, Child Support Enforcement collections, Child Care Mandatory and Matching Funds of the Child Care and Development Fund, Title IV–E Foster Care Maintenance payments, Adoption Assistance payments and Kinship Guardianship Assistance payments, and the eFMAP rates for the Children's Health Insurance Program (CHIP) expenditures. Table 1 gives figures for each of the 50 states, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. This notice reminds states of available disaster-recovery FMAP adjustments for qualifying states, and adjustments available for states meeting requirements for negative growth in total state personal income. At this time, no states qualify for such adjustments.

This notice also contains the increased eFMAPs for CHIP as authorized under the Patient Protection and Affordable Care Act (PPACA) for fiscal years 2016 through 2019 (October 1, 2015 through September 30, 2019).

Programs under title XIX of the Act exist in each jurisdiction. Programs under titles I, X, and XIV operate only in Guam and the Virgin Islands. The percentages in this notice apply to state expenditures for most medical assistance and child health assistance, and assistance payments for certain social services. The Act provides