

is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>, or <http://www.regulations.gov>.

Dated: July 31, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-19244 Filed 8-5-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Program Expansion for the National Center for Medical Home Implementation Cooperative Agreement at the American Academy of Pediatrics

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Single-Case Deviation from Competition Requirement for Program Expansion for the National Center for Medical Home Implementation Cooperative Agreement at the American Academy of Pediatrics, Grant Number U43MC09134.

SUMMARY: HRSA announces its intent to award a program expansion supplement in the amount of \$300,000 for the National Center for Medical Home Implementation (NCMHI) cooperative agreement. The purpose of the NCMHI cooperative agreement, as stated in the funding opportunity announcement, is to: (1) Support a national resource and technical assistance effort to implement and spread the medical home model to all children and youth, particularly children with special health care needs (CSHCN), children who are vulnerable and/or medically underserved, and pediatric populations served by state

public health programs, MCHB, and HRSA; and (2) support activities of the Healthy Tomorrows Partnership for Children Program (HTPCP) grantees to improve children's health through innovative community-based efforts, and community and statewide partnerships among professionals in health, education, social services, government, and business. The purpose of this notice is to award supplemental funds to develop the Rural IMPACT project to support activities related to child health in rural and underserved communities by the American Academy of Pediatrics, the cooperative agreement awardee who serves as the NCMHI, during the budget period of July 1, 2015, to June 30, 2016. The NCMHI is authorized by the Social Security Act, Title V, Sections 501(a)(1)(D) and 501(a)(2)), (42 U.S.C. 701).

The NCMHI is a national resource to implement and spread the medical home model to all children and youth, particularly children with special health care needs and children who are vulnerable and/or medically underserved. The NCMHI supports activities of the Health Tomorrows Partnership for Children Program grantees to improve children's health through innovative community-based efforts, and community and statewide partnerships among professionals in health, education, social services, government, and business.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: The American Academy of Pediatrics.

Amount of the Non-Competitive

Award: \$300,000.

CFDA Number: 93.110.

Current Project Period: July 01, 2008–June 30, 2018.

Period of Supplemental Funding: July 1, 2015–June 30, 2016.

Authority: Social Security Act, Title V, sections 501(a)(1)(D) and 501(a)(2), (42 U.S.C. 701).

Justification: The White House Rural Council is leading a Rural Child Poverty Initiative, the Rural IMPACT Project, to support improved well-being and upward economic mobility of children in rural and tribal communities. In collaboration with the White House Rural Council, HRSA, and the Administration for Children and Families, each using its own authority, used fiscal year (FY) 2015 funds to support a cohort of 10 rural and Tribal communities to provide two-generation, bundled services to children and families in need. Utilizing the two-generation approach, the communities will promote problem solving at the community level by encouraging

pediatric clinicians' participation and public-private partnership, such as the Early Childhood Comprehensive Systems Initiative, Project Launch, and private sector support for improved collaboration and coordination of and access to mental, oral, and physical health and non-clinical resources (e.g. home visiting, early care and education settings such as child care and Head Start, early intervention, child welfare, education) at the community level for children, youth, and their families.

In 2013, following objective review of its application, HRSA awarded to the American Academy of Pediatrics (AAP) cooperative agreement funding for the NCMHI. If approved, this would be the first project expansion supplement for this project.

Through the NCMHI, the AAP is working to link key state and community programs, such as Title V, school-based health centers, Head Start, and Early Intervention, which are critical, natural access points for building and strengthening integrated service delivery systems for women, children, and their families. Working with the Healthy Tomorrows Partnership for Children Program grantees and the AAP Council on Community Pediatrics Rural Health Special Interest Group, the NCMHI supports activities that promote access to quality, patient/family-centered and culturally effective services for children, youth and their families, particularly in rural and underserved communities.

The proposed Rural IMPACT Project activities align with the current project plan, as the NCMHI advances system changes and new initiatives at the community, state, and national levels, building on community partnerships to support family-centered medical home implementation for all children and youth, particularly those underrepresented and from diverse communities (Goal 3). The AAP, working with MCHB, would establish an expert workgroup and operational structure to guide the initiative; develop and issue a solicitation and scoring process and conduct a review of applications to make recommendations for participating communities; develop a quality improvement package; identify systems-level measures to monitor process and progress of individual communities and the initiative as a whole, and provide structured technical assistance to the selected communities.

FOR FURTHER INFORMATION CONTACT:

Marie Y. Mann, MD, MPH, FAAP, Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, Health Resources

and Services Administration, 5600

Fishers Lane, Room 13-103, Rockville, Maryland 20857; MMann@hrsa.gov.

Grantee/organization name	Grant No.	State	FY 2015 authorized funding level	FY 2015 estimated supplemental funding
<i>The American Academy of Pediatrics</i>	U43MC09134	IL	\$800,031	\$300,000

Dated: July 27, 2015.
James Macrae,
Acting Administrator.
 [FR Doc. 2015-19260 Filed 8-5-15; 8:45 am]
BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism: Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 on Alcohol Abuse and Alcoholism Special Emphasis; Panel Review of National Research Service Award Applications.

Date: October 7, 2015.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIAAA, NIH, 5635 Fishers Lane, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Dr. Beata Buzas, Ph.D., Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, NIH, 5635 Fishers Lane; Room 2081, Rockville, MD 20852, (301) 443-2067, bbuzas@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 92.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research

and Research Supports Awards, National Institutes of Health, HHS)

Dated: August 3, 2015.

David Clary,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-19345 Filed 8-5-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Glaucoma, Retinopathy and Retinal Degeneration.

Date: August 25, 2015.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Alessandra C. Rovescalli, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Rm 5205 MSC7846, Bethesda, MD 20892, (301) 435-1021, rovescalla@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special Review: Cognition and Perception.

Date: August 28, 2015.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Weijia Ni, Ph.D., Chief/Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3100, MSC 7808, Bethesda, MD 20892, (301) 594-3292, niw@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 3, 2015.

David Clary,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-19344 Filed 8-5-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism: Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings 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 on Alcohol Abuse and Alcoholism Initial Review Group; Clinical, Treatment and Health Services Research Review Subcommittee.

Date: October 13, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.