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IV. Paperwork Reduction Act of 1995

This draft guidance refers to proposed collections of information described in FDA's July 10, 2012, proposed rule on the UDI system (77 FR 40736), which this draft guidance is intended to interpret. The proposed collections of information in the proposed rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). As required by the PRA, FDA has published an analysis of the information collection provisions of the proposed rule (77 FR 40736 at 40762) and has submitted them for OMB approval (OMB control number 0910-0720).

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It 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>.

Dated: September 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-23058 Filed 9-20-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

State System Development Initiative (SSDI) Grant Program; Single-Case Deviation From Competition Requirements

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

ACTION: Notice of Single-Case Deviation from Competition Requirements for the Maternal and Child Health (MCH) Bureau's States System Development Initiative (SSDI) Grant.

SUMMARY: HRSA will be issuing a non-competitive program expansion supplement for one State SSDI Grant. Approximately \$82,332 in supplemental funding will be made available in the form of a grant to the Department of Health Care Services, Sacramento, California, Grant Number H18MC24474, during the budget period of December 1, 2012, through November 30, 2013.

The SSDI Grant program, CFDA No. 93.110, is authorized by Title V, Social Security Act, Section 501(a)(2); as amended (42 U.S.C. 701(a)(2)).

The SSDI Grant program was developed to complement the Title V MCH Services Block Grant program by assisting state MCH and Children with Special Health Care Needs (CSHCN) programs in the building of state data capacity and infrastructure that support comprehensive, community-based systems of care for all children and their families. SSDI grants to states are intended to not only advance and strengthen data capacity by directing grant resources towards Title V MCH Block Grant program's Health Systems Capacity Indicator (HSCI) #09A (i.e., the ability of states to assure that the MCH programs and Title V agency have access to policy and program relevant information and data), but also to move states forward in developing improved capacity for reporting standardized and quality data that is timely.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Department of Health Care Services, Sacramento, California.

Amount of the Non-Competitive Award: \$82,332.

CFDA Number: 93.110.

Current Project Period: 05/01/2012-11/30/2014.

Period of Supplemental Funding: 12/01/2012-11/30/2013.

Authority: Title V, Social Security Act, Section 501(a)(2); as amended (42 U.S.C. 701).

Justification: Consistent with its legislative purpose to improve the

health of all mothers and children, a key objective of the Title V MCH Block Grant program is to reduce maternal mortality. Due to small numbers for many states, maternal mortality cannot be universally tracked whereas severe, life-threatening maternal morbidity is at least 100 times as common and may be tracked annually for all states. Although a severe maternal morbidity index has been developed using administrative hospital discharge data, a validation in comparison to medical records is needed to determine whether its accuracy is sufficient for use as a national performance measure reported at the state level.

The California Title V MCH program has been a leader in assessing maternal mortality and conducting maternal mortality reviews. In particular, the California Maternal Quality Care Collaborative (CMQCC) is the oldest and largest maternity care collaborative in the country with a longstanding track record of analyzing maternal health data and developing metrics to improve clinical practice and prevent maternal death and injury. The promising work that the California Title V program is doing stands to benefit not only the state but all state MCH programs in promoting a better understanding of the causes of maternal mortality/morbidity and in offering potential solutions. Based on their prior work, established data networks, and sheer size of their birth cohort, the State of California is uniquely qualified to evaluate and make recommendations for a state-level severe maternal morbidity measure.

FOR FURTHER INFORMATION CONTACT:

Scott Snyder, MPH, Division of State and Community Health, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 18-31, Rockville, Maryland 20857; ssnyder@hrsa.gov.

Grantee/organization name	Grant No.	State	FY 2013 authorized funding level	FY 2013 estimated supplemental funding
Department of Health Care Services	H18MC24474	CA	\$100,000	\$82,332

Dated: September 17, 2013.

Mary K. Wakefield,
Administrator.

[FR Doc. 2013-23074 Filed 9-23-13; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Medical Imaging Study Section, October 07, 2013, 08:00 a.m. to October 08, 2013, 05:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on September 10, 2013, FR 78 55268-55270.

The meeting will be held October 7, 2013, 9:30 a.m. to 5:30 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: September 18, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-23081 Filed 9-23-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; 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 of Biomedical Imaging and Bioengineering Special Emphasis Panel; 2014-01 Reducing Health Disparity SBIR Review.

Date: November 8, 2013.

Time: 10:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Ruixia Zhou, Ph.D., Scientific Review Officer, 6707 Democracy Boulevard, Suite 957, Bethesda, MD 20892, 301-496-4773, zhou@mail.nih.gov.

Dated: September 18, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-23083 Filed 9-23-13; 8:45 am]

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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; Neurobiology, genetics, stress and mood/anxiety disorders.

Date: October 10, 2013.

Time: 5:30 p.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Washington, DC Convention Center, 900 10th Street NW., Washington, DC 20001.

Contact Person: Jay Joshi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5196, MSC 7846, Bethesda, MD 20892, (301) 408-9135, joshij@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Non-HIV Microbial Vaccine Development.

Date: October 18, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Scott Jakes, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4198,

MSC 7812, Bethesda, MD 20892, 301-495-1506, jakesse@mail.nih.gov.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Biostatistical Methods and Research Design Study Section.

Date: October 18, 2013.

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

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Inner Harbor, 301 W. Lombard Street, Baltimore, MD 21201.

Contact Person: Tomas Drgon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3152, MSC 7770, Bethesda, MD 20892, 301-435-1017, tdrgon@csr.nih.gov.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Cancer Biomarkers Study Section.

Date: October 18, 2013.

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

Agenda: To review and evaluate grant applications.

Place: Houston JW Marriott, 5150 Westheimer Road, Houston, TX 77056.

Contact Person: Lawrence Ka-Yun Ng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6152, MSC 7804, Bethesda, MD 20892, 301-357-9318, ngkl@csr.nih.gov.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Host Interactions with Bacterial Pathogens Study Section.

Date: October 18, 2013.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Fouad A El-Zaatari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7808, Bethesda, MD 20892, (301) 435-1149, elzaataf@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Risk, Prevention and Health Behavior.

Date: October 18, 2013.

Time: 8:00 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.

Contact Person: Claire E Gutkin, Ph.D., MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3106, MSC 7808, Bethesda, MD 20892, 301-594-3139, gutkincl@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Molecular Neuroscience of Channels and Receptors.

Date: October 18, 2013.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

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