

2015 when the first local transmission was reported in Brazil. Local transmission of ZIKV has also been reported in areas outside of the Americas, including the Pacific Islands of Samoa, American Samoa, Marshall Islands and Tonga, and Cape Verde in Africa, and there are now at least 50 countries and territories worldwide with active local transmission of the virus.

The first local transmission of ZIKV in the United States was reported from Puerto Rico in December 2015, and soon thereafter local transmission was also reported in American Samoa and the U.S. Virgin Islands. In July 2016, the first cases of local transmission of ZIKV occurring in the continental United States were reported from Miami-Dade County in Florida. The possibility of further geographic spread of ZIKV exists in regions where the *Aedes aegypti*, and possibly the *Aedes albopictus*, mosquito is present. In January 2016, ZIKV disease was added to the list of nationally notifiable conditions in the United States as a subtype of Arboviral diseases.

The most common ZIKV disease symptoms include fever, arthralgia, maculopapular rash, and conjunctivitis. In addition, neurological manifestations and congenital anomalies have been associated with ZIKV disease outbreaks. ZIKV infection has been associated with Guillain-Barré syndrome. ZIKV infection during pregnancy is a cause of microcephaly and other serious fetal brain anomalies. Other problems have been detected in pregnancies and among fetuses and infants infected with ZIKV before birth, such as miscarriage, stillbirth, absent or poorly developed brain structures, defects of the eye, hearing deficits, and impaired growth; however, the full clinical spectrum of the effects of ZIKV infection during pregnancy is not yet known.

FDA has identified ZIKV as a transfusion-transmitted infection under § 630.3(l) and RTTI under § 630.3(h)(2). This determination is based on the severity of the disease, risk of transfusion-transmission by blood and blood components, the availability of appropriate screening measures, and significant incidence and prevalence affecting the potential donor population.

The guidance recommends that blood establishments test all donations collected in the United States and its territories with an investigational individual donor nucleic acid test (ID-NAT) for ZIKV under an investigational new drug application (IND), or when available, a licensed test. Alternatively, blood establishments may implement pathogen reduction technology for

platelets and plasma using an FDA-approved pathogen reduction device as specified in the Instructions for Use of the device. If an FDA-approved pathogen reduction device becomes available for Whole Blood or red blood cells, blood establishments may implement pathogen reduction technology for such products rather than testing the donations. Blood establishments implementing these measures may discontinue providing donor educational material with respect to ZIKV and screening donors for ZIKV risk factors such as travel history and deferring them as previously recommended in the February 2016 guidance. Under 21 CFR 630.10(a), if a donor volunteers a recent history of ZIKV infection, a blood establishment must not collect blood or blood components from that donor. For such donors, the guidance recommends a deferral period of 120 days after a positive viral test or the resolution of symptoms, whichever timeframe is longer.

FDA recommends that blood establishments implement the recommendations in the guidance as follows: (1) Blood establishments that collect Whole Blood and blood components in U.S. States and territories with one or more reported locally acquired mosquito-borne cases of ZIKV should implement the recommendations immediately. Blood establishments should cease blood collection until testing or the use of pathogen reduction technology is implemented, consistent with the recommendations in the guidance. As of the date of issuance of the guidance, the recommendations applies to blood establishments that collect Whole Blood and blood components in Florida and Puerto Rico; (2) because of their proximity to areas with locally acquired mosquito-borne cases of ZIKV or because of other epidemiological linkage to ZIKV, such as the number of travel-associated cases reported in a State, blood establishments that collect Whole Blood and blood components in Alabama, Arizona, California, Georgia, Hawaii, Louisiana, Mississippi, New Mexico, New York, South Carolina, and Texas should implement the recommendations as soon as feasible, but not later than 4 weeks after the guidance issue date; and (3) blood establishments that collect Whole Blood and blood components in all other States and territories should implement the recommendations as soon as feasible, but not later than 12 weeks after the date of the issuance of this guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2) without initially seeking prior comment because the Agency has determined that prior public participation is not feasible or appropriate. The guidance represents the current thinking of FDA on "Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 606.100(b) and 606.160(b)(1) have been approved under OMB control number 0910–0795; and the collections of information in 21 CFR 606.122 and 630.30 have been approved under OMB control number 0910–0116.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: August 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–20914 Filed 8–30–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

NAME: National Advisory Committee on Rural Health and Human Services.

DATES AND TIMES:

September 14, 2016, 8:30 a.m.–5:00 p.m.
MT

September 15, 2016, 8:30 a.m.–5:15 p.m.
MT

September 16, 2016, 8:30 a.m.–11:00
a.m. MT

PLACE:

Albuquerque Marriott, 2101 Louisiana
Boulevard NE., Albuquerque, New
Mexico 87110, (505) 881–6800.

STATUS: The meeting will be open to the public.

PURPOSE: The National Advisory Committee on Rural Health and Human Services provides counsel and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas.

AGENDA: The meeting on Wednesday, September 14, will be called to order at 8:30 a.m. by the Chairperson of the Committee, the Honorable Ronnie Musgrove. The Committee will examine the issue of social determinants of health in rural areas. The day will conclude with a period of public comment at approximately 5:00 p.m.

The Committee will break into subcommittees and depart for site visits Thursday morning, September 15, at approximately 8:30 a.m. Subcommittees will visit the Presbyterian Medical Services Cuba Health Center in Cuba, New Mexico; the Laguna Pueblo, a federally recognized Native American tribe of the Pueblo people in Laguna, New Mexico; and the Guadalupe County Hospital in Santa Rosa, New Mexico. The day will conclude at the Albuquerque Marriott with the period of public comment at approximately 5:15 p.m.

On Friday, September 16, at 8:30 a.m., the Committee will meet at the Albuquerque Marriott to summarize key findings from the site visits and develop a work plan for the next quarter.

FOR FURTHER INFORMATION CONTACT:

Steve Hirsch, MSLS, Administrative Coordinator, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, 5600 Fishers Lane, 17W41D, Rockville, MD 20857, Telephone (301) 443–0835, Fax (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Pierre Joseph at the Federal Office of Rural Health Policy (FORHP) via telephone at (301) 945–0897 or by email at PJoseph@hrsa.gov. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable

accommodations, should notify the contact person listed above at least 10 days prior to the meeting. The Committee meeting agenda will be posted on the Committee's Web site at <http://www.hrsa.gov/advisorycommittees/rural/>.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–20911 Filed 8–30–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Mental Health Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Mental Health Council.

Date: September 20, 2016.

Open: 9:00 a.m. to 1:00 p.m.

Agenda: Presentation of the NIMH Director's Report and discussion of NIMH program and policy issues.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Closed: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Jean G. Noronha, Ph.D., Director, Division of Extramural Activities, National Institute of Mental Health, NIH,

Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892–9609, 301–443–3367, jnoronha@mail.nih.gov.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/index.shtml, where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: August 24, 2016.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–20878 Filed 8–30–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center For Complementary & Integrative Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Complementary and Integrative Health.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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