

this notice finalizes the draft guidance dated January 2019.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "ANDA Submissions—Amendments and Requests for Final Approval to Tentatively Approved ANDAs." 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. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs> or <https://www.regulations.gov>.

Dated: September 22, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020-21470 Filed 9-28-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice To Announce Supplemental Award To Support Training and Technical Assistance To Address Clinical Workforce Development

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

ACTION: Announcing supplemental award to support training and technical assistance to address clinical workforce development.

SUMMARY: HRSA provided supplemental funding to Community Health Center, Inc. (CHCI), a currently-funded National Training and Technical Assistance Partner (NTTAP) award recipient. CHCI will expand training and technical assistance (T/TA) to health centers and HRSA-funded State and Regional Primary Care Associations (PCAs) to support implementation of a tool developed for health centers to assess and improve their readiness to engage in health professional training programs and address national health care workforce shortages.

FOR FURTHER INFORMATION CONTACT: Tracey Orloff, Director, HRSA, Strategic Partnerships Division, Office of Quality Improvement, at TOrloff@hrsa.gov or (301) 443-3197.

SUPPLEMENTARY INFORMATION:

Recipient of the Award: Community Health Center, Inc.

Amount of Non-Competitive Award: \$320,000.

Period of Supplemental Funding: August 2020 to June 2022.

CFDA Number: 93.129.

Authority: Section 330(l) of the Public Health Service Act, 42 U.S.C. 254b(l).

Justification: The National Center for Health Workforce Analysis estimates a shortage of over 23,000 primary care physician positions by 2025. Residency programs are needed for health centers to address health care workforce shortages that limit their ability to deliver comprehensive, culturally competent, high quality primary health care services.

CHCI created the Readiness to Train Assessment Tool (RTAT™) for health centers to assess their own readiness to engage in health professional training programs and use the results to manage their workforce shortages. Supplemental funding is necessary to ensure timely implementation of the RTAT™ in order to complete the data collection, analysis, and results dissemination needed for health centers to address critical workforce shortages. As the organization that developed the RTAT™, and the only NTTAP currently funded to provide enhanced T/TA on clinical workforce development to health centers, CHCI has the necessary expertise, organizational systems, and structure in place to immediately expand T/TA efforts in this area.

Thomas J. Engels,

Administrator.

[FR Doc. 2020-21514 Filed 9-28-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Centers for Disease Control and Prevention (CDC)/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) has scheduled a public meeting.

DATES: November 5, 2020, 2:00 p.m.–5:15 p.m. Eastern Time (ET) and November 6, 2020, 2:00 p.m.–5:15 p.m. ET. The deadline for online registration is 12:00 p.m. ET on November 2, 2020.

ADDRESSES: This meeting will be held virtually. Please visit the meeting information page to register: <https://chacfall2020.org>.

FOR FURTHER INFORMATION CONTACT:

Theresa Jumento, Senior Public Health Advisor, HIV/AIDS Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301-443-5807; or CHACAdvisoryComm@hrsa.gov.

SUPPLEMENTARY INFORMATION: CHAC was established under section 222 of the Public Health Service Act, [42 U.S.C. 217a], as amended.

The purpose of CHAC is to advise the Secretary, HHS; the Director, CDC; and the Administrator, HRSA regarding objectives, strategies, policies, and priorities for HIV, viral hepatitis, and other STDs; prevention and treatment efforts including surveillance of HIV infection, viral hepatitis, and other STDs, and related behaviors; epidemiologic, behavioral, health services, and laboratory research on HIV, viral hepatitis, and other STDs; identification of policy issues related to HIV/viral hepatitis/STD professional education, patient healthcare delivery, and prevention services; agency policies about prevention of HIV, viral hepatitis and other STDs; treatment, healthcare delivery, and research and training; strategic issues influencing the ability of CDC and HRSA to fulfill their missions of providing prevention and treatment services; programmatic efforts to prevent and treat HIV, viral hepatitis, and other STDs; and support to the agencies in their development of responses to emerging health needs related to HIV, viral hepatitis, and other STDs.

During the November 5–6, 2020, meeting, CHAC will discuss community engagement activities related to the President's initiative on "Ending the HIV Epidemic: A Plan for America" and the COVID-19 pandemic. CHAC will also discuss the needs and challenges of HIV prevention and care for women. Agenda items are subject to change as priorities dictate. Refer to the CHAC meeting information page for any updated information concerning the meeting.

While this meeting is open to the public, advance registration is required. Members of the public will have the opportunity to provide comments. Requests to offer oral comments will be accepted in the order they are received and may be limited as time allows.

Public participants may also submit written statements as further described below. To submit written comments or to request time for an oral comment at the meeting, please register online by 12:00 p.m. ET on October 28, 2020.

Information about CHAC can be found on the CHAC website at <https://www.cdc.gov/maso/facm/facmCHACHSPT.html>. Visit the meeting information page for additional details <https://chacfall2020.org>. Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Theresa Jumento at the email address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020-20943 Filed 9-28-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Drug Abuse Special Emphasis Panel; NIDA SEP for Career Development (K99/R00 and K12 applications).

Date: November 4, 2020.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sindhu Kizhakke Madathil, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, 3 WFN 9th Floor, MSC 6021, Bethesda, MD 20892, (301) 827-5702, sindhu.kizhakkemadathil@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist

Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: September 23, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-21497 Filed 9-28-20; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meetings

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the President's Cancer Panel.

The meetings will be held as virtual meetings and are open to the public. Individuals who plan to view the virtual meetings and need special assistance or other reasonable accommodations to view the meetings should notify the Contact Person listed below in advance of the meetings. The meetings can be accessed by clicking on the following link: <https://nci.rev.vbrick.com/#/webcasts/presidentscancerpanel>.

Name of Committee: President's Cancer Panel.

Date: November 2, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: Improving Resilience and Equity in Cancer Screening: Lessons from COVID-19 and Beyond (Day 1—Colorectal Cancer).

Place: National Cancer Institute, 31 Center Drive, Building 31, Room 11A48, Rockville, MD 20850, (Virtual Meeting).

Access to Meeting: <https://nci.rev.vbrick.com/#/webcasts/presidentscancerpanel>.

Contact Person: Maureen R. Johnson, Ph.D., Executive Secretary, President's Cancer Panel, Special Assistant to the Director, National Cancer Institute, NIH, 31 Center Drive, Room 11A48 MSC 2590, Bethesda, MD 20892, 240-781-3327, johnsonr@mail.nih.gov.

Name of Committee: President's Cancer Panel.

Date: November 4, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: Improving Resilience and Equity in Cancer Screening: Lessons from COVID-19 and Beyond (Day 2—Colorectal Cancer).

Place: National Cancer Institute, 31 Center Drive, Building 31, Room 11A48, Rockville, MD 20850 (Virtual Meeting).

Access to Meeting: <https://nci.rev.vbrick.com/#/webcasts/presidentscancerpanel>.

Contact Person: Maureen R. Johnson, Ph.D., Executive Secretary, President's Cancer Panel, Special Assistant to the Director, National Cancer Institute, NIH, 31 Center Drive, Room 11A48 MSC 2590, Bethesda, MD 20892, 240-781-3327, johnsonr@mail.nih.gov.

Name of Committee: President's Cancer Panel.

Date: November 9, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: Improving Resilience and Equity in Cancer Screening: Lessons from COVID-19 and Beyond (Day 1—Cervical Cancer).

Place: National Cancer Institute, 31 Center Drive, Building 31, Room 11A48, Rockville, MD 20850, (Virtual Meeting).

Access to Meeting: <https://nci.rev.vbrick.com/#/webcasts/presidentscancerpanel>.

Contact Person: Maureen R. Johnson, Ph.D., Executive Secretary, President's Cancer Panel, Special Assistant to the Director, National Cancer Institute, NIH, 31 Center Drive, Room 11A48 MSC 2590, Bethesda, MD 20892, 240-781-3327, johnsonr@mail.nih.gov.

Name of Committee: President's Cancer Panel.

Date: November 10, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: Improving Resilience and Equity in Cancer Screening: Lessons from COVID-19 and Beyond (Day 2—Cervical Cancer).

Place: National Cancer Institute, 31 Center Drive, Building 31, Room 11A48, Rockville, MD, 20850 (Virtual Meeting).

Access to Meeting: <https://nci.rev.vbrick.com/#/webcasts/presidentscancerpanel>.

Contact Person: Maureen R. Johnson, Ph.D., Executive Secretary, President's Cancer Panel, Special Assistant to the Director, National Cancer Institute, NIH, 31 Center Drive, Room 11A48 MSC 2590 Bethesda, MD 20892, 240-781-3327, johnsonr@mail.nih.gov.

Name of Committee: President's Cancer Panel.

Date: November 16, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: Improving Resilience and Equity in Cancer Screening: Lessons from COVID-19 and Beyond (Day 1—Breast Cancer).

Place: National Cancer Institute, 31 Center Drive, Building 31, Room 11A48, Rockville, MD 20850, (Virtual Meeting).

Access to Meeting: <https://nci.rev.vbrick.com/#/webcasts/presidentscancerpanel>.

Contact Person: Maureen R. Johnson, Ph.D., Executive Secretary, President's Cancer Panel, Special Assistant to the Director, National Cancer Institute, NIH, 31 Center Drive, Room 11A48, MSC 2590, Bethesda, MD 20892, 240-781-3327, johnsonr@mail.nih.gov.

Name of Committee: President's Cancer Panel.

Date: November 18, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: Improving Resilience and Equity in Cancer Screening: Lessons from COVID-19 and Beyond (Day 2—Breast Cancer).