in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 301–796–5003, Fax: 301–847–8443, *Graham.Thompson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the publication of a report providing options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the human drug and biosimilar biologic review programs. FDA, in both the PDUFA VI and BsUFA II commitment letters, committed to obtaining this report and publishing it before September 30, 2020. These commitments were also codified in the statute authorizing these programs (sections 736(c)(2)(C) and 744H(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)(2)(C) and 379j–52(c)(2)(B)).

PDUFA and BsUFA, (referred to collectively here as ''UFA(s)'') each establish fee amounts for each fiscal year. Although the specifics for each UFA are different, the process for each generally involves the following: Taking an annual base revenue amount and adjusting that base revenue amount for inflation and other UFA-specific adjustments to establish a target revenue amount for the fiscal year for the UFA. The target revenue amount sets the total amount of fee revenue for the UFA that FDA expects to collect for that fiscal year. The target revenue amount is then divided up based on UFA-specific processes to set the individual fee amounts for the fiscal year.

While this process creates a relatively predictable source of UFA fee revenue for FDA, it also requires a method for adjustment to account for changes in workload. For example, without an adjustment for workload, during a period of growth in regulatory submissions the target revenue will remain fixed and a higher number of submissions results in the same total revenue collected; in other words, the Agency would have more work while fee revenue remains fixed and would not be able to afford hiring the additional staff required to maintain review timeline performance.

This issue was recognized by PDUFA-program stakeholders, and in 2003, the first year of PDUFA III, a Workload Adjustment was introduced. This adjustment created a means to adjust the annual PDUFA target revenue to account for long-term changes in the volume of certain regulatory submissions. Although an important mechanism to help ensure that the PDUFA target revenue keeps pace with regulatory submissions, the Workload Adjustment has been a topic in each PDUFA reauthorization negotiation since its inception. As such, it has undergone a number of changes, notably the addition and later removal of a factor to adjust revenue based on the complexity of submissions. It has also been the subject of a number of studies. A theme emerging from these studies identified the Workload Adjuster methodology as suboptimal, but the best method reasonably possible based on the data available to FDA at that time.

In PDUFA VI (fiscal years 2018 to 2022), FDA made commitments to help improve the available data and in turn the adjuster methodology. These commitments included establishing a Resource Capacity Planning capability and modernizing FDA's activity-based time reporting to provide better data to inform current and likely future resource needs. PDUFA VI changed the name of the adjustment to the *Capacity Planning Adjustment,* established an interim methodology for the early years of PDUFA VI, and outlined a process to implement a new fee adjustment methodology.

The process calls for FDA to obtain, through a contract with an independent accounting or consulting firm, an evaluation of options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the human drug review program. Booz Allen Hamilton was commissioned to produce this report. The report is publicly available on FDA's website at: *https://www.fda.gov/industry/fda-user-fee-programs/resource-capacity-planning-and-modernized-time-reporting,* and FDA will review public comments on the report. After review of the public comments, FDA can then implement a new robust methodology for assessing the resource needs of the program that results from sustained increases in PDUFA workload, as appropriate and warranted in light of comments we receive.

Within BsUFA II (fiscal years 2018 to 2022), FDA made a commitment to use this same study to also assess options and recommendations for a new methodology to assess changes in the resource and capacity needs of the biosimilar biological product review program. Whereas PDUFA has an interim Capacity Planning Adjustment in place now, BsUFA does not have and has not had an adjustment designed to accomplish similar goals for the BsUFA program. Like with the process outlined with PDUFA, FDA can also implement an adjustment methodology following the publication of the report and review of any public comments, as appropriate and warranted in light of comments we receive.

Dated: April 1, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–07175 Filed 4–3–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Council on Graduate Medical Education

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

ACTION: Notice; correction.

SUMMARY: The Council on Graduate Medical Education (COGME) meeting previously announced as in-person and webinar/conference call on Tuesday, April 28, 2020, and Wednesday, April 29, 2020, has changed its format, date, and time. The meeting will now be a one-day webinar and conference call only on Wednesday, April 29, 2020, from 12:00 p.m.–5:00 p.m. Eastern Time. The webinar link, conference dial-in number, meeting materials, and agenda will be available on the COGME website: *https://www.hrsa.gov/advisory-committees/graduate-medical-edu/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Kennita Carter, MD, Senior Advisor and Designated Federal Official, Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–945–9505; or *BHWCOGME@hrsa.gov.*

Correction: Meeting will be a one-day webinar and conference call only rather than two-days and in-person as previously announced.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–07147 Filed 4–3–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Council on Nurse Education and Practice

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 National Advisory Council on Nurse Education and Practice (NACNEP) has scheduled a writing subcommittee public meeting. Information about NACNEP, the agenda, and materials for this meeting can be found on the NACNEP website at *https://www.hrsa.gov/advisory-committees/nursing/index.html.*

DATES: April 20, 2020, 10:00 a.m.–2:00 p.m. Eastern Time (ET).

ADDRESSES: This meeting will be held by teleconference, and/or Adobe Connect webinar.

- *Webinar link. https://www.hrsa.gov/advisory-committees/nursing/meetings.html.*
- *Conference call-in number:* 1–888–455–4141; Passcode: FACA Meeting.

FOR FURTHER INFORMATION CONTACT: Camillus Ezeike, Ph.D., LL.M. J.D., RN, PMP, Designated Federal Official, NACNEP, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–2886; or *BHWNACNEP@hrsa.gov.*

SUPPLEMENTARY INFORMATION: NACNEP provides advice and recommendations to the Secretary of HHS and the U.S. Congress on policy issues related to the activities carried out under Title VIII of the Public Health Service (PHS) Act, including the range of issues relating to the nurse workforce, education, and practice improvement. NACNEP also prepares and submits an annual report to the Secretary of HHS and Congress describing its activities, including NACNEP's findings and recommendations concerning activities under Title VIII of the PHS Act.

During the April 20, 2020, meeting, the writing sub-committee of NACNEP will review recent literature and hear from an expert speaker on the topic of its 17th Report to Congress, *Preparing Nurse Faculty, and Addressing the Shortage of Nurse Faculty and Clinical Preceptors.* Agenda items are subject to change as priorities dictate. Refer to the NACNEP website for updated information concerning the meeting. The final agenda will be posted at least 14 calendar days before the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to NACNEP should be sent to Camillus Ezeike using the contact information above at least 3 business days before the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–07115 Filed 4–3–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 84 FR 49535–49540 dated September 20, 2019).

HRSA is making changes within the Federal Office of Rural Health Policy (FORHP) in order to realign the functions for the management of emerging rural health program initiatives, including rural substance abuse programs.

This reorganization updates the organization, functions, and delegation of authority of FORHP (RH). Specifically this reorganization (1) establishes the Rural Strategic Initiatives Division; and (2) updates the functional statement for the Federal Office of Rural Health Policy (RH).

Chapter RH—Federal Office of Rural Health Policy

Section RH.10 Organization

Delete the organization for FORHP (RH) in its entirety and replace with the following:

The Federal Office of Rural Health Policy is headed by the Associate Administrator, who reports directly to the Administrator, HRSA. FORHP includes the following components:

(1) Office of the Associate Administrator (RH)
(2) Hospital State Division (RH1);
(3) Community-Based Division (RH2);
(4) Office for the Advancement of Telehealth (RH4);
(5) Policy Research Division (RH5);
(6) Administrative Operations Division (RH6); and
(7) Rural Strategic Initiatives Division (RH7).

Section RH.20 Function

Delete the functional statement for FORHP (RH) and in its entirety and replace with the following:

Federal Office of Rural Health Policy (RH)

Office of the Associate Administrator (RH)

The Federal Office of Rural Health Policy (FORHP) is responsible for the overall leadership and management of the Office. FORHP serves as a focal point within HHS for rural health-related issues and as a principal source of advice to the Secretary for coordinating efforts to strengthen and improve the delivery of health services to populations in the nation's rural areas. FORHP provides leadership within HHS and with stakeholders in providing information and counsel related to access to, and financing and quality of, health care to rural populations. Specifically, the Office of the Associate Administrator (1) provides staff support to the National Advisory Committee on Rural Health and Human Services; (2) stimulates and coordinates interaction on rural health activities and programs in the agency, Department and with other federal agencies; (3) establishes and maintains a resource center for the collection and dissemination of the latest information and research findings related to the delivery of health services in rural areas; (4) ensures successful dissemination of appropriate information technology advances, such as telehealth or electronic health records systems; (5) monitors the health information