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 379–52(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 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.

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 on 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