claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not 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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling the Center for Biologics Evaluation and Research at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Julia Beaver, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2100, Silver Spring, MD 20993–0002, 240–402–0489 or Stephen Ripley, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant Treatment.'' This draft guidance provides recommendations to sponsors regarding the development of drugs regulated by CDER and CBER for the adjuvant treatment of renal cell carcinoma. The draft guidance includes recommendations regarding eligibility criteria, choice of comparator, followup imaging assessments, determination of disease recurrence, analyses of disease-free survival (DFS), and interpretation of trial results. Although FDA may consider endpoints other than DFS for the adjuvant treatment of renal cell carcinoma, this guidance is focused on clinical trials with DFS as the primary efficacy endpoint.

Adjuvant renal cell carcinoma clinical trials are an active area of research. There is significant variability in the design, conduct, and analysis of these trials, including the eligibility criteria, radiological disease assessments, the definition of disease recurrence, and the date used to define the DFS endpoint in these trials. Consistency in these aspects within and across trials may facilitate interpretation of trial results. These issues were discussed at an FDA-National Cancer Institute public workshop held on November 28, 2017. This draft guidance provides recommendations on these issues to facilitate adjuvant renal cell carcinoma clinical trials.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant Treatment.'' 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 draft guidance refers to previously approved FDA collections of information. 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. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: September 28, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21840 Filed 10–1–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Class Deviation From Competition Requirements for HRSA–15–021: Quality Improvement Capacity for Impact Project

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

ACTION: Notice.

SUMMARY: HRSA is providing supplemental funding for one year to the current recipients of HRSA–15–021, Quality Improvement Capacity for Impact Project.

FOR FURTHER INFORMATION CONTACT: Austin Demby, Ph.D., MPH, Acting Director,

Office of Global Health, Office of the Administrator, HRSA, 5600 Fishers Lane, 09N09, Rockville, MD 20857, Phone: (301) 443–0581, Email: *ademby@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Recipients of the Award: The Regents of the University of California San Francisco (UCSF–U1NHA31422) and the Trustees of Columbia University in the City of New York (ICAP–U1NHA28555).

Amount of Award: HRSA has awarded two grants totaling $6 million noted in Table 1.

Period of Supplemental Funding: September 30, 2020—September 29, 2021,

CFDA Number: 93.266

TABLE 1—RECIPIENTS AND AWARD AMOUNTS

Grant number	Award recipient name	Extension length	Award amount
UCSF–U1NHA31422	The Regents of the University of California San Francisco.	1 Year	$4,000,000
ICAP–U1NHA28555	Trustees of Columbia University in the City of New York.	1 Year	2,000,000

Justification: The purpose of these cooperative agreements is to save lives, prevent HIV infections, and accelerate progress toward achieving HIV/AIDS epidemic control in more than 50 countries around the world. Recipients have completed certain project activities, but evaluation and transition to scale-up has been interrupted by the COVID–19 pandemic and associated country-specific restrictions. This notice extends the current project period for HRSA–15–021, Quality Improvement Capacity for Impact Project, by one year until September 29, 2021, to ensure the orderly conclusion of these projects while facilitating virtual stakeholder engagement during the COVID–19 pandemic.

Authority: United States President's Emergency Plan for AIDS Relief authorized by Public Law 108–25 (the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003) [22 U.S.C. 7601, *et seq.*]; and Public Law 110–293 (the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008), as reauthorized and amended by Public Law 113–56 (the President's Emergency Plan for AIDS Relief Stewardship and Oversight Act of 2013). See, *e.g.,* 22 U.S.C. 7603 and 22 U.S.C. 2151b–2(b)(1)(B), 2151b–2(c)(1), and 2151b–2(d)(6)(G)(ii).

Thomas J. Engels,

Administrator.

[FR Doc. 2020–21778 Filed 10–1–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Recharter for the Council on Graduate Medical Education

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

ACTION: Notice of recharter.

SUMMARY: In accordance with the Federal Advisory Committee Act, HHS is hereby giving notice that the Council on Graduate Medical Education (COGME) has been rechartered. The effective date of the renewed charter is September 30, 2020.

FOR FURTHER INFORMATION CONTACT: Shane Rogers, Designated Federal Official (DFO), Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA. Anyone requesting information may reach Mr. Rogers by mail at 5600 Fishers Lane, 15N142, Rockville, Maryland 20857; by phone at 301–443–5260; or by email at *SRogers@hrsa.gov*

SUPPLEMENTARY INFORMATION: COGME makes recommendations to the Secretary of HHS (Secretary) and Congress on matters specified by section 762 of Title VII of the Public Health Service (PHS) Act. Issues addressed by COGME include (1) the supply and distribution of physicians in the United States; (2) current and future shortages or excesses of physicians in medical and surgical specialties and subspecialties; (3) issues relating to foreign medical school graduates; (4) appropriate federal policies with respect to the matters specified in (1), (2), and (3) above, including policies concerning changes in the financing of undergraduate and graduate medical education (GME) programs and changes in the types of medical education training in GME programs; (5) appropriate efforts to be carried out by hospitals, schools of medicine, schools of osteopathic medicine, and accrediting bodies with respect to the matters specified in (1), (2), and (3) above, including efforts for changes in undergraduate and GME programs; and (6) deficiencies in, and needs for improvements in, existing databases concerning the supply and distribution of, and postgraduate training programs for, physicians in the United States and steps that should be taken to eliminate those deficiencies. Not later than September 30, 2023, and not less than every 5 years thereafter, COGME shall submit a report with recommendations to the Secretary, and to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives. Additionally, COGME encourages entities providing GME to conduct activities to voluntarily achieve the recommendations of COGME; and develops, publishes, and implements performance measures, develops and publishes guidelines for longitudinal evaluations, and recommends appropriation levels for certain programs under Title VII of the PHS Act.

The renewed charter for COGME was approved on September 30, 2020, which will also stand as the filing date. Recharter of the COGME gives authorization for the Council to operate until September 30, 2022.

A copy of the COGME charter is available on the COGME website at *https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/graduate-medical-edu/cogme-charter.pdf.* A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is *http://www.facadatabase.gov/.*

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–21773 Filed 10–1–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice That HRSA Will Not Fund HRSA–20–083: Quality Improvement Solutions for Sustained Epidemic Control Project

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

ACTION: Notice.

SUMMARY: HRSA has decided not to provide funding for HRSA–20–083 *Quality Improvement Solutions for Sustained Epidemic Control Project,*