agency of the time and place of the hearing, and the issues to be considered. If we subsequently notify the state Medicaid agency of additional issues that will be considered at the hearing, we will also publish that notice in the **Federal Register**.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as amicus curiae must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The notice to South Carolina announcing an administrative hearing to reconsider the disapproval of its SPAs reads as follows:

Robert M. Kerr
Director, South Carolina Department of Health and Human Services, Post Office Box 8206, Columbia, SC 29202–8206

Dear Mr. Kerr:

I am responding to the July 19, 2021 request for reconsideration of the decision to disapprove South Carolina's State Plan amendment (SPA) 19–0004–A. South Carolina SPA 19–0004–A was submitted to the Centers for Medicare & Medicaid Services (CMS) on June 28, 2019 and disapproved on May 21, 2021. I am scheduling a hearing on the request for reconsideration to be held on January 12, 2022, at the Department of Health and Human Services, Division of Medicaid Field Operations, South, Centers for Medicare & Medicaid Services, Division of Medicaid and Children's Health Operations, 61 Forsyth St., Suite 4T20, Atlanta, Georgia 30303–8909.

I am designating Mr. Benjamin R. Cohen as the presiding officer. If these arrangements present any problems, please contact Mr. Cohen at (410) 786–3169. In order to facilitate any communication that may be necessary between the parties prior to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing. If the hearing date is not acceptable, Mr. Cohen can set another date mutually agreeable to the parties. The hearing will be governed by the procedures prescribed by federal regulations at 42 CFR part 430.

This SPA requested CMS approval to update annual supplemental teaching physician (STP) payment program using the Average Commercial Rate (ACR) methodology effective April 1, 2019. This SPA included Greenville Memorial Hospital, and Palmetto Health Richland/USC.

The issues to be considered at the hearing are whether South Carolina SPA 19–0004–A is inconsistent with the requirements of:

- Section 1902(a)(2) of the Social Security Act (the Act), providing that the state plan must assure adequate funding for the non-federal share of expenditures from state or local sources, such that the lack of adequate funds from local sources will not result in lowering the amount, duration, scope, or quality of care and services available under the plan.
- Sections 1903(a) and 1905(b) of the Act, providing that states receive a statutorily determined Federal Medicaid Assistance Percentage (FMAP) for allowable state expenditures on medical assistance.
- Section 1903(w)(1)(A)(i)(I) of the Act, providing that, notwithstanding the previous provisions of section 1903, for purposes of determining the amount to be paid to a State (as defined in paragraph (7)(D)) under subsection (a)(1) for quarters in any fiscal year, the total amount expended during such fiscal year as medical assistance under the State plan (as determined without regard to section 1903(w)) shall be reduced, inter alia, by the sum of any revenues received by the State (or by a unit of local government in the State) during the fiscal year from provider-related donations other than bona fide provider-related donations, as defined in section 1903(w)(2)(B).
- Section 1903(w)(2)(A) of the Act, providing that, in section 1903(w), except as provided in section 1903(w)(6), the term ''provider-related donation'' means any donation or other voluntary payment (whether in cash or in kind) made (directly or indirectly) to a State or unit of local government by—(i) a health care provider (as defined in section 1903(w)(7)(B)), (ii) an entity related to a health care provider (as defined in section 1903(w)(7)(C)), or (iii) an entity providing goods or services under the State plan for which payment is made to the State under paragraph (2), (3), (4), (6), or (7) of section 1903(a).
- Section 1903(w)(2)(B) of the Act, providing that, for purposes of section 1903(w)(1)(A)(i)(I), the term ''bona fide provider-related donation'' means a provider-related donation that has no direct or indirect relationship (as determined by the Secretary) to payments made under title XIX to that provider, to providers furnishing the same class of items and services as that provider, or to any related entity, as established by the State to the satisfaction of the Secretary. The Secretary may by regulation specify types of provider-related donations described in the previous sentence that will be considered to be bona fide provider-related donations.
- Section 1903(w)(6)(A) of the Act, providing that, notwithstanding the provisions of section 1903(w), the Secretary may not restrict States'' use of funds where such funds are derived from State or local taxes (or funds appropriated to State university teaching hospitals) transferred from or certified by units of government within a State as the non-Federal share of expenditures under title XIX, regardless of whether the unit of government is also a health care provider, except as provided in section 1902(a)(2), unless the transferred funds are derived by the unit of government from donations or taxes that would not otherwise be recognized as the non-Federal share under section 1903.
- 42 CFR 433.54(b), (c)(2), and (c)(3), providing that provider-related donations will be determined to have no direct or indirect relationship to Medicaid payments if those donations are not returned to the individual provider, the provider class, or related entity under a hold harmless provision or practice, as described in 42 CFR 433.54(c). A hold harmless practice exists if, inter alia, all or any portion of the Medicaid payment to the donor, provider class, or related entity, varies based only on the amount of the donation, including where Medicaid payment is conditional on receipt of the donation; or if the State (or other unit of government) receiving the donation provides for any direct or indirect payment, offset, or waiver such that the provision of that payment, offset, or waiver directly or indirectly guarantees to return any portion of the donation to the provider (or other parties responsible for the donation).

In the event that CMS and the State come to agreement on resolution of the issues which formed the basis for disapproval, these SPAs may be moved to approval prior to the scheduled hearing.

Sincerely,
Chiquita Brooks-LaSure,
Administrator
cc: Benjamin R. Cohen

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Section 1116 of the Social Security Act (42 U.S.C. section 1316; 42 CFR section 430.18) (Catalog of Federal Domestic Assistance Program No. 13.714. Medicaid Assistance Program.)

Dated: November 26, 2021.

Evell J. Barco Holland,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2021–26136 Filed 11–30–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2809]

Advisory Committee; Patient Engagement Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

renewal of the Patient Engagement Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Patient Engagement Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the October 6, 2023, expiration date.

DATES: Authority for the Patient Engagement Advisory Committee would have expired on October 6, 2021, unless the Commissioner had formally determined that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Letise Williams, Office of the Center Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5407, Silver Spring, MD 20993–0002, 301–796–8398, *Letise.Williams@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Patient Engagement Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective devices for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

The Committee provides advice to the Commissioner on complex scientific issues relating to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes, device-related quality of life measures, or health status issues are among the topics that may be considered by the Committee. The Committee provides relevant skills and perspectives to improve communication of benefits, risks, and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

Pursuant to its Charter the Committee shall consist of a core of nine voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities who are knowledgeable in areas such as clinical research, patient experience, healthcare needs of patient groups in the United States, or are experienced in the work of patient and health professional organizations, methodologies for patient-reported outcomes and eliciting patient preferences, and strategies for communicating benefits, risks and clinical outcomes to patients and research subjects, as well as other relevant areas. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees, representative or Ex-Officio members. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. The Commissioner or designee shall also have the authority to select from a group of individuals nominated by industry to serve temporarily as non-voting members who are identified with industry interests. The number of temporary members selected for a particular meeting will depend on the meeting topic.

The Commissioner or designee shall also have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) Expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/committees-and-meeting-materials/patient-engagement-advisory-committee* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: November 23, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26118 Filed 11–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Administration

Privacy Act of 1974; System of Records

AGENCY: Office of the Assistant Secretary for Administration, Department of Health and Human Services (HHS).

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, the U.S. Department of Health and Human Services (HHS) is establishing a new departmentwide system of records, 09–90–2103, Accommodation Records About HHS Civilian Employees, Contractors and Visitors.

DATES: The new system of records is applicable December 1, 2021, subject to a 30-day period in which to comment on the routine uses.

ADDRESSES: The public should address written comments by email to *beth.kramer@hhs.gov* or by mail to Beth Kramer, HHS Privacy Act Officer, FOIA/Privacy Act Division—Suite 729H, Office of the Assistant Secretary for Public Affairs, 200 Independence Ave. SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: General questions may be submitted to Beth Kramer, HHS Privacy Act Officer,