established additional burden associated with §§ 494.70(c) and 494.180(k); these were quantified in the preceding information collection which expired in 2024 (OMB Control Number 0938–0386). Since these regulations were not finalized due to litigation, they are no longer in effect. Therefore, we took out these sections from this package as they do not impose any burden.

An additional revision to the ESRD CfCs at 42 CFR 494 was precipitated by final rule, ''*Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers,*'' published September 16, 2016 (CMS–3178–F). This rule established the creation and maintenance of an Emergency Preparedness Plan at 494.62(a), an Emergency Preparedness Policies and Procedures document at 494.62(b), an Emergency Preparedness Communication Plan at 494.62(c), a training program 494.62(d), and documentation of training exercises 494.62(e). These information collections are in separate package, OMB Control number 0938–1325.

On July 5, 2024, revisions to the CfC were proposed in ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model'', (CMS–1805–P). This rule proposed to expand coverage of home dialysis services to patients with acute kidney injury (AKI). Since the ESRD CfCs apply to dialysis facilities, not to people with ESRD, this rule proposes to revise language in the CfCs to allow beneficiaries with AKI to utilize home dialysis. Specifically, we refer to facilities abiding by the ESRD CfCs as 'dialysis facilities' opposed to 'ESRD facilities and all patients seeking services from dialysis facilities as 'patients' rather than 'ESRD patients.' There is no ICR burden associated with these changes however we made confirming changes to the language in this package.

The CfCs are used by Federal (CMS), State surveyors (employed by State survey agencies), or CMS authorized accrediting organizations as a basis for determining whether a dialysis facility qualifies for approval or re-approval under Medicare. Surveyors make an in-person visit to the dialysis facility to perform the complete survey.

The preceding information collection, which expired on March 31, 2024, estimated the total annual hourly burden as 1,260,491 hours at a cost of $64,839,657. We revise this to 800,621 hours at a cost of $49,638,502. The reduction in hours and cost is largely due to removing the burden estimates that no longer apply. *Form Number:* CMS–R–52 (OMB Control Number: 0938–0386); *Frequency:* Annually; *Affected Public:* Private sector—Business or other for-profit; *Number of Respondents:* 8,048; *Total Annual Responses:* 215,591; *Total Annual Hours:* 800,621 (For policy questions regarding this collection contact Claudia Molinar at 410–786–8445.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of information Collection:* Expanding Access to Women's Health Grant; *Use:* On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA), and on March 30, 2010, the Health Care and Education Reconciliation Act of 2010 was also signed into law (collectively referred to as the ''ACA''). The ACA includes a number of provisions that reform the health insurance markets and provide Federal consumer protections through amendments to title XXVII of the Public Health Service Act (PHS Act) and corresponding amendments to the Employee Retirement Income Security Act and the Internal Revenue Code. The ACA also includes significant grant funding for States to work with the Federal Government to implement the Federal market reforms and consumer protections.

Section 1003 of the ACA adds a new section 2794 to the PHS Act entitled, ''Ensuring That Consumers Get Value for Their Dollars.'' Specifically, section 2794(a) requires the Secretary of the Department of Health and Human Services (the Secretary) (HHS), in conjunction with the States, to establish a process for the annual review of health insurance premiums to protect consumers from unreasonable rate increases. Section 2794(c) directs the Secretary to carry out a program to award grants to States. The data collection (quarterly and final reports) are a source of information on the State's progress with meeting CMS expectations for the Expanding Access to Women's Health Grant. The reports describe significant advancements towards the State's goal of enhancing and expanding access to reproductive and maternal health coverage and services from the beginning of the grant period through the completion of the grant period. The data collection is imperative to CMS being able to assess the State's progress, barriers, and updates on measurable objectives. Without the data collection, CMS will be unable to efficiently monitor the State's progress. It will also inhibit CMS' ability to support and share opportunities of best practices with other States. *Form Number:* CMS–10901 (OMB control number 0938–NEW); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 15; *Total Annual Responses:* 68; *Total Annual Hours:* 840. (For policy questions regarding this collection contact Jim Taing at *James.Taing@cms.hhs.gov.*)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–30502 Filed 12–20–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA), Center for Drug Evaluation and Research (CDER), Office of Medical Policy (OMP) has modified their organizational structure. The new organizational structure was approved by the Secretary of Health and Human Services on November 19, 2024.

FOR FURTHER INFORMATION CONTACT: Jennifer Wade, Acting Director, Division of Reorganizations and Delegations of Authority, Office of Budget, Office of Finance, Budget, and Acquisitions, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–731–0192.

SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D–B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is revised to reflect the FDA's reorganization of the CDER, OMP.

The reorganization will improve FDA's ability to carry out its public health mission by realigning and dedicating resources within the organization to modernize clinical trials. The clinical trial innovation work tracks will place DCI at the forefront to robustly meet policy development, implementation, and analysis needs in areas such as Artificial Intelligence (AI), Digital Health Technologies (DHTs), Real-World Evidence (RWE), and other rapidly advancing sectors in the dynamic clinical trial ecosystem.

The CDER, OMP, Office of Medical Policy Initiatives retitled the Division of Clinical Trial Quality to the Division of Clinical Innovations.

The reorganization will enhance the office's ability to attract and retain a diverse workforce representative of our nation and bring like scientists and policy experts together from across the organization, thereby facilitating collaboration and efficient use of shared resources while advancing key innovations in drug development. By developing responsive policies, the Division of Clinical Innovations will modernize the policy environment to ensure that CDER is providing the needed regulatory perspective to guide the appropriate use of such tools and technologies.

The FDA's CDER, OMP has been restructured as follows:

DCDH ORGANIZATION. The CDER OMP (DCDH) is headed by the Director, OMP and includes the following:

Office of Medical Policy (DCDH)
Office of Prescription Drug Promotion (DCDHA)
Division of Advertising and Promotion Review II (DCDHAA)
Division of Advertising and Promotion Review I (DCDHAB)
Division of Promotion Policy, Research and Operations (DCDHAC)
Office of Medical Policy Initiatives (DCDHB)
Division of Medical Policy Development (DCDHBA)
Division of Medical Policy Programs (DCDHBB)
Division of Clinical Innovations (DCDHBC)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete Staff Manual Guide can find it on FDA's website at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

Authority: 44 U.S.C. 3101.

Xavier Becerra,

Secretary of Health and Human Services.

[FR Doc. 2024–30333 Filed 12–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation

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 Secretary's Advisory Council on Blood Stem Cell Transplantation (ACBSCT or Council) has scheduled a public meeting. Information about ACBSCT and the agenda for the meeting can be found on the ACBSCT website at *https://bloodstemcell.hrsa.gov/about/advisory-council.*

DATES: Thursday, January 23, 2025, 3:00 p.m.–5:00 p.m. Eastern Standard Time.

ADDRESSES: This meeting will be held virtually by webinar. A link to register and join the meeting will be posted at least 10 days prior to the meeting at *https://bloodstemcell.hrsa.gov/about/advisory-council.*

FOR FURTHER INFORMATION CONTACT: Shelley Tims Grant, Designated Federal Official, Division of Transplantation, Health Systems Bureau, HRSA, 5600 Fishers Lane, 8W–67, Rockville, Maryland 20857; 301–443–8036; or *ACBSCTHRSA@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACBST provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under the authority of 42 U.S.C. 274k (Section 379 of the Public Health Service Act), Public Law 109–129, as amended. The Council may transmit its recommendations through the Administrator of HRSA on matters related to the activities of the C.W. Bill Young Cell Transplantation Program and National Cord Blood Inventory.

The agenda for the January 23, 2025, meeting is being finalized and may include the following topics: graft versus host disease and late effects, strategies for selecting cord blood units for transplantation, HHS' approach for reviewing the state of the science and recommendations on the appropriateness of the inclusion of adult stem cells and birthing tissues as new types of therapies in the C.W. Bill Young Cell Transplantation Program, and other areas to increase blood stem cell donation and transplantation. Agenda items are subject to change as priorities dictate. Refer to ACBSCT's website for any updated information concerning the meeting. Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meetings; 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 ACBSCT should be sent to Shelley Tims Grant, using the contact information above at least 3 business days prior to the meeting. Individuals who plan to attend and need special assistance or other reasonable accommodations should notify ACBSCT at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–30604 Filed 12–20–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60 Day Notice for Extension of Fast Track Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery: Indian Health Service Customer Service Satisfaction and Similar Surveys

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments. Request for extension of approval.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to take this opportunity to comment on the information collection Office of Management and Budget (OMB) Control Number 0917–