To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html*.

2. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–P–0015A Medicare Current Beneficiary Survey

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Current Beneficiary Survey; *Use:* CMS is the largest single payer of health care in the United States. The agency plays a direct or indirect role in administering health insurance coverage for more than 120 million people across the Medicare, Medicaid, CHIP, and Exchange populations. A critical aim for CMS is to be an effective steward, major force, and trustworthy partner in supporting innovative approaches to improving quality, accessibility, and affordability in healthcare. CMS also aims to put patients first in the delivery of their health care needs.

The Medicare Current Beneficiary Survey (MCBS) is the most comprehensive and complete survey available on the Medicare population and is essential in capturing data not otherwise collected through our operations. The MCBS is a nationally-representative, longitudinal survey of Medicare beneficiaries that we sponsor and is directed by the Office of Enterprise Data and Analytics (OEDA). The survey is usually conducted in-person but can also be conducted by phone. It captures beneficiary information whether aged or disabled, living in the community or facility, or serviced by managed care or fee-for-service. Data produced as part of the MCBS are enhanced with our administrative data (*e.g.,* fee-for-service claims, prescription drug event data, enrollment, etc.) to provide users with more accurate and complete estimates of total health care costs and utilization. The MCBS has been continuously fielded for more than 28 years, encompassing over 1 million interviews and more than 100,000 survey participants. Respondents participate in up to 11 interviews over a four-year period. This gives a comprehensive picture of health care costs and utilization over a period of time.

The MCBS continues to provide unique insight into the Medicare program and helps CMS and our external stakeholders better understand and evaluate the impact of existing programs and significant new policy initiatives. In the past, MCBS data have been used to assess potential changes to the Medicare program. For example, the MCBS was instrumental in supporting the development and implementation of the Medicare prescription drug benefit by providing a means to evaluate prescription drug costs and out-of-pocket burden for these drugs to Medicare beneficiaries. Beginning in 2021, this proposed revision to the clearance will add a few new measures to existing questionnaire sections and will add a new COVID–19 Questionnaire section previously approved by OMB on August 7, 2020 under Emergency Clearance 0938–1379. The revisions will result in an increase in respondent burden due to the addition of the new items. *Form Number:* CMS–P–0015A (OMB control number: 0938–0568); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 13,656; *Total Annual Responses:* 35,998; *Total Annual Hours:* 53,176. (For policy questions regarding this collection contact William Long at 410–786–7927.)

Dated: September 9, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–20273 Filed 9–14–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Assessing Models of Coordinated Services for Low-Income Children and Their Families (AMCS) (0970–0535)

AGENCY: Office of Planning, Research, and Evaluation; Administration for Children and Families; Health and Human Services (HHS).

ACTION: Request for public comment.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting an extension to continue collecting data for the study, Assessing Models of Coordinated Services for Low-Income Children and Their Families (AMCS). Data collection has been delayed due to the COVID–19 pandemic and will not be complete by the current expiration date of October 31, 2020. There are no changes proposed to the current instruments.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: Through AMCS, ACF seeks to learn more about how states and communities coordinate early care and education, family economic security, and/or other health and human

services to most efficiently and effectively serve the needs of low-income children and their families. ACF aims to understand strategies used to support partnerships, including the federal barriers to agency collaboration. In support of achieving these goals, the study team is conducting ''virtual site visits'' with six programs that offer coordinated services. The study team will gather information through interviews with program staff members, such as agency leaders or frontline staff, and focus groups with parents.

Data collection activities will include up to six program ''virtual site visits.'' ''Virtual site visits'' include semi-structured interviews with up to 30 total staff at each site and focus groups with 8–10 parents at each site. Semi-structured interviews with program and partner staff will obtain in-depth information about the goals and objectives of programs, the services provided, how the coordinated services are implemented, how staffing is managed, data use, and any facilitators and barriers to coordination. Focus groups with parents participating in the program will provide the opportunity to learn about how parents perceive the program; how it meets their needs; what benefits they gain from the program; and how they enroll, participate, and progress through the program.

Respondents: Lead program and partner program staff members working in six programs across the United States that coordinate early care and education services with family economic security services and/or other health and human services, as well as parents receiving services from these programs. Staff respondents will be selected with the goal of having staff represent each level of the organization. Parents who have participated in the program for at least 6 months and who receive early childhood services and at least one other program service will be invited to participate in focus groups.

ANNUAL BURDEN ESTIMATES

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Master Virtual Site Visit Interview Protocol	180	1	2	360
Parent Virtual Focus Group Protocol	60	1	1	60

Estimated Total Annual Burden Hours: 420.

Authority: 42 U.S.C. 9858(a)(5).

John M. Sweet, Jr.,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–20266 Filed 9–14–20; 8:45 am]

BILLING CODE 4184–23–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1153]

Post-Marketing Pediatric-Focused Product Safety Reviews; Establishment of a Public Docket; Request for Comments; Correction

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of September 2, 2020. The document announced the availability of post-marketing pediatric-focused safety reviews of products posted between September 23, 2019, and September 1, 2020, on FDA's website but not presented at the September 15, 2020, Pediatric Advisory Committee meeting. The document was published with the incorrect product name for one of the post-marketing pediatric-focused safety reviews listed under Center for Biologics Evaluation and Research. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Marieann Brill, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993, 240–402–3838.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of September 2, 2020 (85 FR 54580), appearing on page 54580 in FR Doc. 2020–19835, the following correction is made:

On page 54581, in the first column, under Center for Biologics Evaluation and Research, ''9. QPAN H5N1 Vaccine (Influenza A (H5N1) virus monovalent vaccine, adjuvanted)'' is corrected to read ''9. Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted.''

Dated: September 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–20329 Filed 9–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that TRIKAFTA (elexacaftor/tezacaftor/ivacaftor), manufactured by Vertex Pharmaceutical, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4061, Fax: 301–796–9856, email: *althea.cuff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that TRIKAFTA (elexacaftor/tezacaftor/ivacaftor),