++ The Joint Commission's capacity to adequately fund required surveys.

++ The Joint Commission's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ The Joint Commission's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ The Joint Commission's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

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

Dated: December 7, 2021.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2021–26822 Filed 12–9–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–R–153, CMS–10561 and CMS–10657]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by January 10, 2022.

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.

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.*

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

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Use Review (DUR) Program; *Use:* States must provide for a review of drug therapy before each prescription is filled or delivered to a Medicaid patient. This review includes screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Pharmacists must make a reasonable effort to obtain, record, and maintain Medicaid patient profiles. These profiles must reflect at least the patient's name, address, telephone number, date of birth/age, gender, history, *e.g.,* allergies, drug reactions, list of medications, and pharmacist's comments relevant to the individual's drug therapy.

The States must conduct RetroDUR which provides for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, inappropriate or medically unnecessary care. Patterns or trends of drug therapy problems are identified and reviewed to determine the need for intervention activity with pharmacists and/or physicians. States may conduct interventions via telephone, correspondence, or face-to-face contact.

Annual reports are submitted to CMS for the purposes of monitoring compliance and evaluating the progress of States' DUR programs. The

information submitted by States is reviewed and results are compiled by CMS in a format intended to provide information, comparisons, and trends related to States' experiences with DUR. States benefit from the information and may enhance their programs each year based on State reported innovative practices that are compiled by CMS from the DUR annual reports.

In this 2021 collection of information request, we revised certain FFS, MCO, and Abbreviated MCO survey questions. While a few questions were added to the surveys to address GAO (U.S. Government Accountability Office) recommendations, other aspects of the survey changes include grammar and formatting edits. Overall, we are not revising our currently approved burden estimates.

Form Number: CMS–R–153 (OMB control number: 0938–0659); *Frequency:* Yearly, quarterly, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 663; *Total Annual Hours:* 41,004. (For policy questions regarding this collection contact Mike Forman at 410–786–2666.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Supporting Statement for Essential Community Provider Data Collection to Support QHP Certification for PYs 2022–2024; *Use:* Standards for Essential Community Provider (ECP) requirements are codified at 45 CFR 156.235. Issuers must contract with a certain percentage, as determined by HHS, of the available ECPs in the plan's service area. For plan years 2022–2024, Health and Human Services (HHS) will continue to solicit qualified ECPs to complete and submit the HHS ECP provider petition in order to be added to the HHS ECP list, or update required data fields to remain on the list, resulting in a more robust and accurate listing of the universe of available ECPs from which issuers select to satisfy the ECP standard. HHS will continue to collect such data directly from providers through the online ECP provider petition. *Form Number:* CMS–10561; *Frequency:* Annually; *Affected Public:* Private sector, Business or other for-profits, and Not-for-profit Institutions; *Number of Respondents:* 12,408; *Number of Responses:* 12,408; *Total Annual Hours:* 3,140. (For questions regarding this collection, contact Deborah Hunter at 443–386–3651).

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* The State Flexibility to Stabilize the Market Cycle I and II Grant Program Reporting; *Use:* Section 1003 of the Affordable Care Act (ACA) adds a new section 2794 to the Public Health Service Act (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. Section 2794(c)(2)(B) specifies that any appropriated Rate Review Grant funds that are not fully obligated by the end of FY 2014 shall remain available to the Secretary for grants to States for planning and implementing the insurance market reforms and consumer protections under Part A of title XXVII of the (PHS Act. States that are awarded funds under this funding opportunity are required to provide CMS with four quarterly reports and one annual report (except for the last year of the grant) until the end of the grant period detailing the state's progression towards planning and/or implementing the pre-selected market reforms under Part A of Title XXVII of the PHS Act. A final report is due at the end of the grant period. *Form Number:* CMS–10657 (OMB control number: 0938–1366); *Frequency:* Annually and Quarterly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 34; *Total Annual Responses:* 170; *Total Annual Hours:* 2,312. (For policy questions regarding this collection contact Jim Taing at *James.Taing@cms.hhs.gov*.)

Dated: December 7, 2021.

William N. Parham, III,

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

[FR Doc. 2021–26816 Filed 12–9–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1518]

Development of Anti-Infective Drug Products for the Pediatric Population; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Development of Anti-Infective Drug Products for the Pediatric Population.'' The purpose of this guidance is to provide general recommendations on the development of anti-infective drug products for pediatric patients. The guidance addresses enrollment strategies, extrapolation of efficacy, safety database, and other considerations to help facilitate pediatric anti-infective drug product development. This guidance finalizes the draft guidance of the same title issued on June 30, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on December 10, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management