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.*).

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: September 22, 2021.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2021–20957 Filed 9–27–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–R–70, CMS–R–72 and CMS–10783]

Agency Information Collection Activities: Proposed Collection; 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by November 29, 2021.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

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 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–R–70
- Information Collection Requirements in HSQ–110, Acquisition, Protection and Disclosure of Peer review Organization Information and Supporting Regulations

CMS–R–72
- Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36, 478.42, QIO Reconsiderations and Appeals

CMS–10783
- Generic Beneficiary and Family Centered-Care Quality Improvement Organization (BFCC–QIO) Data Collection Research

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:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements in HSQ–110, Acquisition, Protection and Disclosure of Peer review Organization Information and Supporting Regulations; *Use:* The Peer Review Improvement Act of 1982 authorizes quality improvement organizations (QIOs), formally known as peer review organizations (PROs), to acquire information necessary to fulfill their duties and functions and places limits on disclosure of the information. The QIOs are required to provide notices to the affected parties when disclosing information about them. These requirements serve to protect the rights of the affected parties. The information provided in these notices is used by the patients, practitioners and providers to: Obtain access to the data maintained and collected on them by the QIOs; add additional data or make changes to existing QIO data; and reflect in the QIO's record the reasons for the QIO's disagreeing with an individual's or provider's request for amendment. *Form Number:* CMS–R–70 (OMB control number: 0938–0426); *Frequency:* Reporting—On occasion; *Affected Public:* Business or other for-profits; *Number of Respondents:* 53,850; *Total Annual Responses:* 436,984; *Total Annual Hours:* 404,208. (For policy questions regarding this collection contact Kimberly Harris at 617–565–1285.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36, 478.42, QIO Reconsiderations and Appeals; *Use:* In the event that a beneficiary, provider, physician, or other practitioner does not agree with the initial determination of a Quality Improvement Organization (QIO) or a QIO subcontractor, it is within that party's rights to request

reconsideration. The information collection requirements 42 CFR 478.18, 478.34, 478.36, and 478.42, contain procedures for QIOs to use in reconsideration of initial determinations. The information requirements contained in these regulations are on QIOs to provide information to parties requesting the reconsideration. These parties will use the information as guidelines for appeal rights in instances where issues are actively being disputed. *Form Number:* CMS–R–72 (OMB control number: 0938–0443); *Frequency:* Reporting—On occasion; *Affected Public:* Individuals or Households and Business or other for-profit institutions; *Number of Respondents:* 20,129; *Total Annual Responses:* 60,489; *Total Annual Hours:* 22,014. (For policy questions regarding this collection contact Kimberly Harris at 617–565–1285).

3. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Generic Beneficiary and Family Centered-Care Quality Improvement Organization (BFCC–QIO) Data Collection Research; *Use:* The purpose of this submission is to request approval for generic clearance that covers a program of data collection activities to obtain feedback from a broad audience that may include, but will not be limited to Medicare beneficiaries, their family, health care providers and other key stakeholders who have used or may use and have been impacted by the BFCC–QIO services and its offerings. This data collection effort is part of a strategic plan to obtain direct feedback from Medicare beneficiaries, their family, health care providers and other key stakeholders on QIO process improvement efforts and their satisfaction with the services provided by these BFCC–QIOs. Feedback obtained will be used to improve the BFCC QIO program. With the approval of this clearance, the Division of Beneficiary Reviews and Care Management (DBRCM) will be able to maintain a proactive process for rapid data collection to inform the work of the BFCC–QIO program around new and existing initiatives, as well as providing rapid feedback on service delivery and satisfaction for continuous improvement of the BFCC–QIO program.

The BFCC–QIO program is statutorily mandated to improve the quality of healthcare services Medicare beneficiaries receive. BFCC–QIOs provide the foundational level of quality in the health care system by investigating quality of care complaints made by Medicare beneficiaries and their families; by providing an avenue for appeals if they feel they are being released from a facility too soon; by requesting for immediate advocacy services when they have concerns about their care that need a quick resolution; and by providing care management services to help people with Medicare navigate the healthcare system and coordinate their care. The BFCC–QIOs provide these essential services for beneficiaries and families of the national Medicare program.

This generic clearance will cover a program of qualitative (in-depth interviews and focus group interviews), and quantitative methods (surveys) to obtain feedback from a wide range of audience that may include, but will not be limited to Medicare beneficiaries, their family, healthcare providers and any other key audiences that would support CMS in informing and improving QIO services, and any new and existing initiatives. *Form Number:* CMS–10783 (OMB control number: 0938–NEW); *Frequency:* Occasionally; *Affected Public:* Individuals and Households; *Number of Respondents:* 16,800; *Total Annual Responses:* 191,200; *Total Annual Hours:* 59,400. For policy questions regarding this collection, contact Yewande Oladeinde at 410–786–2157.)

Dated: September 22, 2021.

William N. Parham, III,

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

[FR Doc. 2021–20978 Filed 9–27–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0689]

Public Workshop: Analgesic Clinical Trial Designs, Extrapolation, and Endpoints in Patients From Birth to Less Than Two Years of Age

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Analgesic Clinical Trial Designs, Extrapolation, and Endpoints in Patients from Birth to Less Than Two Years of Age.'' The purpose of the public workshop is to discuss the state of science, data gaps, and challenges in drug development for drugs intended to treat acute pain in patients less than 2 years of age.

DATES: The public workshop will be held virtually on October 13 and 14, 2021, from 10 a.m. to 2 p.m. Eastern Standard Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held in virtual format only and will not be held at a specific location. Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this public meeting via an online teleconferencing platform. The public workshop will be held at *https://go.umd.edu/analgesic-clinical-trial.*

FOR FURTHER INFORMATION CONTACT: Heather Buck at *Heather.Buck@fda.hhs.gov,* 301–796–1413 or Kerri-Ann Jennings at *Kerri-Ann.Jennings@fda.hhs.gov,* 301–796–2919, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 22, Rm. 6467, Silver Spring, MD 20903–0002.

SUPPLEMENTARY INFORMATION:

I. Background

In 2009, FDA convened a scientific workshop with experts in pediatric pain, pediatric clinical trial design, pediatric ethics, and pediatric drug development [1]. Based on the available data at the time, the expert panel recommended extrapolation of efficacy in patients 2 years and older, relying on matching effective drug exposures in adults. The current approach to study drugs with well-established mechanisms of action, such as opioids, non-steroidal anti-inflammatory drugs (NSAIDS), acetaminophen, and local anesthetics, relies on matching safe and effective drug exposures in adults to support the efficacy of drugs used to treat acute pain in pediatric patients at least 2 years of age. Controlled efficacy trials are only required in patients from birth to less than 2 years of age. When controlled efficacy trials are needed, FDA has recommended an ''add-on'' design using opioid-sparing calculation rather than the change in pain intensity used in efficacy trials of analgesics in adults.

Despite these advances in clinical trial design, there continues to be unmet needs in the availability of products to treat acute pain, especially in patients less than 2 years of age. There is currently only one analgesic labeled for use in patients less than 2 years of age: Ibuprofen is approved for the treatment

[1] Berde, CB, et.al., Pediatrics 2012 Feb;129(2):354–64. *https://www.fda.gov/advisory-committees/advisory-committee-calendar/april-12-2016-pediatric-advisory-committee-meeting-announcement-04122016-04122016.*