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 *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. 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–10105 National Implementation of the In-Center Hemodialysis CAHPS Survey

CMS–10407 Summary of Benefits and Coverage and Uniform Glossary

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 without change of a currently approved collection; *Title of Information Collection:* National Implementation of the In-Center Hemodialysis CAHPS Survey; *Use:* The Centers for Medicare & Medicaid Services (CMS) is requesting clearance from the Office of Management and Budget (OMB) to continue the In-center Hemodialysis CAHPS (ICH CAHPS) Survey to measure patients' experience of care with in-center hemodialysis (ICH) facilities. Data collected in the national implementation of the ICH CAHPS Survey are used for the following purposes: To provide a source of information from which selected measures can be publicly reported to beneficiaries as a decision aid for dialysis facility selection; to aid facilities with their internal quality improvement efforts and external benchmarking with other facilities; to provide CMS with information for monitoring and public reporting purposes; and to support the ESRD value-based purchasing program. *Form Number:* CMS–10105 (OMB control number: 0938–0926); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 108,800; *Total Annual Responses:* 108,800; *Total Annual Hours:* 58,753. (For policy questions regarding this collection contact Julia Zucco at 410–786–6677.)

2. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Summary of Benefits and Coverage and Uniform Glossary; *Use:* This information collection will ensure that consumers shopping for or enrolled in private, individually purchased, or non-federal governmental group health plan coverage receive the consumer protections of the Affordable Care Act. Employers, employees, and individuals will use this information to compare coverage options prior to selecting coverage and to understand the terms of, and extent of medical benefits offered by, their coverage (or exceptions to such coverage or benefits) once they have coverage. CMS recently received OMB approval for a non-substantive change to the SBC calculator. Specifically, CMS requested that issuers begin using an updated 2020 SBC calculator starting on or after January 1, 2020. However, at this time, CMS is alerting issuers to immediately discontinue use of the 2020 calculator. Until further notice from CMS, issuers should revert back to using the 2017 SBC Calculator and all associated materials (including the 2017 SBC Calculator Excel file, the Guides and Narratives for the coverage examples, and the calculator instructions) to calculate coverage example costs for the SBC. *Form Number:* CMS–10407 (OMB control number: 0938–1146); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 128,511; *Total Annual Responses:* 24,433,233; *Total Annual Hours:* 41,551. (For policy questions regarding this collection contact Jessica Weinberg at 301–492–4404.)

Dated: May 8, 2019.

William N. Parham, III,

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

[FR Doc. 2019–09781 Filed 5–10–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Procedural Justice-Informed Alternatives to Contempt Demonstration Project Data Collection (OMB #0970–0505)

AGENCY: Office of Child Support Enforcement; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data as part of the rigorous evaluation of the *Procedural Justice-Informed Alternatives to Contempt* (PJAC) demonstration.

DATES: Comments due by July 12, 2019. In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Office of Child Support Enforcement (OCSE) within the Administration for Children and Families (ACF) is proposing a data collection activity as part of the Procedural Justice-Informed Alternatives to Contempt (PJAC)

Demonstration. In September 2016, OCSE issued grants to five state child support agencies to provide alternative approaches to the contempt process with the goal of increasing noncustodial parents' compliance with child support orders by building trust and confidence in the child support agency and its processes. OCSE also awarded a grant to support a rigorous evaluation of PJAC. The PJAC Demonstration is a five-year project that allows grantees and OCSE to learn whether incorporating principles of procedural justice into child support business practices increases reliable child support payments, reduces arrears, minimizes the need for continued enforcement actions and sanctions, and reduces the use of contempt proceedings.

The PJAC demonstration will yield information about the efficacy of applying procedural justice principles via a set of alternative services to the current use of a civil contempt process to address nonpayment of child support. It will generate knowledge regarding how the PJAC intervention operates, the effects the alternative services have, and whether the benefits of this approach exceed the costs. The information gathered will help inform future policy decisions related to the contempt process within the field of child support enforcement.

PJAC demonstration will include three interconnected evaluation components:

1. Implementation Study. The implementation study will provide a detailed description of the PJAC intervention—how it is implemented, whether it was implemented as intended, participant characteristics, the contexts in which it is operated, how treatment differed from the status quo, and the implications of PJAC practices. The study will identify the intervention features and conditions necessary for effective replication or improvement of the intervention. Key elements of the implementation study include: A Management Information System (MIS) for random assignment and data collection on participant engagement in PJAC activities; semi-structured interviews with staff from child support agencies and selected partner organizations; separate semi-structured interviews with study participants and the custodial parents connected to their child support case to learn about their experiences with and perceptions of the child support program; and a staff questionnaire to gather quantitative information on the implementation of PJAC services and staff experiences.

2. Impact Study. The impact study will provide rigorous estimates of the effectiveness of the PJAC intervention using an experimental research design. Noncustodial parents whose cases are being referred to the contempt process will be randomly assigned to either a program group that is offered PJAC services or to a control group that is offered business-as-usual services. Random assignment will require child support program staff to complete a brief data entry protocol. The impact study will rely on administrative data from state and county child support programs, court records, criminal justice records, and data from the National Directory of New Hires. Administrative records data will be used to estimate impacts on child support payments, enforcement actions, contempt proceedings, and jail stays.

3. Benefit-Cost Study. The benefit-cost study will estimate the costs and benefits associated with the implementation and impact of the PJAC interventions. The study will examine the costs and benefits from the perspective of the government, noncustodial parents, custodial parents, and society. Pertinent benefits and costs will be added together to determine the net value of the program for each perspective. Key outcomes to be assessed include the cost of PJAC interventions, costs for contempt actions, child support payments from noncustodial parents (program and control), court costs, and jail time, among others. The benefit-cost study will rely on the results of the impact study, analysis of participation data from the MIS, and results of a staff time study to quantify various PJAC-related costs and benefits.

This notice is specific to the following data collection activities: The noncustodial parent participant interviews (these interview topic guides were approved under a previous submission and require content modification which also significantly lowers the collective public burden hours); the staff survey; the staff time study; and the custodial parent interviews. Data collection activities that were previously approved by OMB, following public comment, are the staff data entry on participant baseline information, study MIS to track receipt of services, staff and community partner interview topic guide, the participant interview topic guide, and the participant survey tracking letter. A participant survey has been eliminated from the data collections plans, so the OMB-approved participant survey tracking letter will no longer be used.

Respondents: Respondents include study participants, child support program staff at the six PJAC demonstration sites, custodial parents associated with study participants, and the federal Office of Child Support Enforcement.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours
Noncustodial parent participant interview	60	1	1	60
Staff Survey	20	1	.5	10
Staff time study	30	1	1.5	45
Custodial parent interview	60	1	1	60

Estimated Total Annual Burden Hours: 175

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 1315.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–09756 Filed 5–10–19; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1875]

Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments.'' The purpose of the public meeting is to meet performance commitments included in the Prescription Drug User Fee Act (PDUFA) VI, Biosimilar User Fee Act (BsUFA) II, and Generic Drug User Fee Amendments (GDUFA) II. The public meeting will include presentations from FDA on the 5-year plans for the PDUFA VI, BsUFA II, and GDUFA II; the Agency's progress in implementing resource capacity planning and modernized time reporting; and the results of the fiscal year (FY) 2018 evaluation of PDUFA, BsUFA, and GDUFA resource management. The Agency will also address the impact of the modernized fee structure changes on the PDUFA and BsUFA programs and report on the contribution of the BsUFA spending trigger to the BsUFA program.

DATES: The public meeting will be held on June 7, 2019, from 9 a.m. to 12 p.m. Submit either electronic or written comments on this public meeting by July 8, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 8, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 8, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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 Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–1875 for ''Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New