

development of public reports that will be published by the Departments on prescription drug reimbursements for plans and coverage, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under the plans or coverage. The 2021 interim final rules, “Prescription Drug and Health Care Spending” (2021 interim final rules), issued by the Departments and the Office of Personnel Management (OPM) implement the provisions of section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act, as enacted by section 204 of Title II of Division BB of the CAA. OPM joined the Departments in issuing the 2021 interim final rules, requiring Federal Employees Health Benefits (FEHB) carriers to report information about prescription drug and health care spending, premiums, and plan enrollment in the same manner as a group health plan or health insurance issuer offering group or individual health insurance coverage.

The 2023 Prescription Drug Data Collection (RxDC) Reporting Instructions reflect changes for the 2023 reference year and beyond. As a result of removing first-year implementation costs and burdens that were incurred prior to 2024, it is estimated that there will be a decrease in total three-year average annual burden from 1,684,080 to 668,952. *Form Number:* CMS–10788 (OMB Control Number: 0938–1407); *Frequency:* Annually; *Affected Public:* Private Sector; *Number of Respondents:* 356; *Number of Responses:* 356; *Total Annual Hours:* 668,952. (For policy questions regarding this collection

contact Christina Whitefield at 202–536–8676.)

William N. Parham, III,
Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget (OMB) Review; Generic Clearance for the Comprehensive Child Welfare Information System (CCWIS) Technical Assistance and Review Process (OMB #: 0970–0568)

AGENCY: Children’s Bureau, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Children’s Bureau (CB), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) is requesting a 3-year extension of the Generic Clearance for the Comprehensive Child Welfare Information System (CCWIS) Technical Assistance (TA) and Review Process, (OMB #0970–0568, expiration 4/30/2024) and all approved information collections under this generic. There are no changes requested to the terms of the umbrella generic or to the currently approved information collections.

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. You can also obtain copies of the proposed collection of information by emailing infocollection@acf.hhs.gov. Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The CCWIS Technical Assistance and Review information collection includes two components.

- The CCWIS Assessment Review (CAR) Process.
- TA tools for title IV–E agencies to self-assess their conformity to CCWIS project and design requirements at 45 CFR 1355.52–3.

The CCWIS requirements at 45 CFR 1355.55 require the review, assessment, and inspection of the planning, design, development, installation, operation, and maintenance of each CCWIS project on a continuing basis. The Advance Planning Document (APD) regulations at 45 CFR 95.621 require periodic reviews of state and local agency methods and practices to ensure information systems, including CCWIS, are utilized for purposes consistent with proper and efficient administration.

This request is for an extension with no changes to the umbrella generic and all currently approved information collections, which can be found here: https://www.reginfo.gov/public/do/PRAICList?ref_nbr=202311-0970-010.

Respondents: Title IV–E agencies under the Social Security Act.

Annual Burden Estimates

ANNUAL BURDEN—CURRENTLY APPROVED INFORMATION COLLECTIONS

Instrument	Total number of respondents	Total number of responses per respondent (3 years)	Average burden hours per response	Total burden hours	Annual burden hours
CCWIS Self-Assessment—Administration	55	1	10	550	183
CCWIS Self-Assessment—Adoption	55	1	10	550	183
CCWIS Self-Assessment—Case Management	55	1	10	550	183
CCWIS Self-Assessment—Foster Care and Service Provider Management	55	1	10	550	183
CCWIS Self-Assessment—Intake	55	1	10	550	183
CCWIS Self-Assessment—Investigation	55	1	10	550	183
CCWIS Self-Assessment: Child Welfare Contributing Agency (CWCA)	55	1	10	550	183
CCWIS Self-Assessment: Data Exchanges	55	1	10	550	183
CCWIS Self-Assessment: Data Quality	55	1	10	550	183

ANNUAL BURDEN—CURRENTLY APPROVED INFORMATION COLLECTIONS—Continued

Instrument	Total number of respondents	Total number of responses per respondent (3 years)	Average burden hours per response	Total burden hours	Annual burden hours
CCWIS Self-Assessment: Design Requirements	55	1	24	1320	440
CCWIS Self-Assessment: Financial	55	1	10	550	183
CCWIS Self-Assessment:					
Reporting	55	1	10	550	183
CCWIS Self-Assessment: Security	55	1	10	550	183
CCWIS Self-Assessment: Title IV–E Foster Care Maintenance Eligibility	55	1	10	550	183
CCWIS Self-Assessment: User Experience	55	1	10	550	183
Total Annual Burden for Currently Approved Generics				9020	3,002

ANNUAL BURDEN—POTENTIAL ADDITIONAL INFORMATION COLLECTION REQUESTS

Instrument	Total number of respondents	Total number of responses per respondent (3 years)	Average burden hours per response	Total burden hours	Annual burden hours
Future Tools to be developed	55	1	10	550	183

Authority: 5 U.S.C. 301; 42 U.S.C. 470, 620 *et seq.*, 622(b), 629b(a), 652(b), 654A, 670 *et seq.*, 671(a), 1302, and 1396a(a).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–09226 Filed 4–29–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1243]

Safety Testing of Human Allogeneic Cells Expanded for Use in Cell-Based Medical Products; Draft 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 draft document entitled “Safety Testing of Human Allogeneic Cells Expanded for Use in Cell-Based Medical Products; Draft Guidance for Industry.” Allogeneic cells of human origin may be expanded in culture to manufacture medical products consisting of live cells, inactivated cells, cell lysates, or other cell-based materials such as cell-derived particles. The draft guidance document provides sponsors of allogeneic cell-based medical products

recommendations for determining the appropriate cell safety testing to support an investigational new drug application (IND) or a biologics license application (BLA). Cell safety testing should be based on a risk analysis that considers the expansion potential of the cells, the reagents that are used to expand the cells in culture, and the number of individuals the cell-based medical product is capable of treating.

DATES: Submit either electronic or written comments on the draft guidance by July 29, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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 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–2024–D–1243 for “Safety Testing of Human Allogeneic Cells Expanded for Use in Cell-Based Medical Products; Draft Guidance for Industry.” Received comments 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, 240–402–7500.