purpose of the forms and provide general guidance on completion.

Respondents: Healthcare providers (pediatricians, medical specialists, and dentists), Care Provider Program Staff

Annual Burden Estimates

ESTIMATED OPPORTUNITY TIME FOR RESPONDENTS

Instrument	Respondent	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Medical Assessment Form	Pediatricians, General	300	840	0.22	166,320	55,440
	Medical specialist, General	750	22	0.22	10,890	3,630
Dental Assessment Form ...	Dentists	250	64	0.12	5,760	1,920

Estimated Total Annual Burden Hours: 60,990.

ESTIMATED RECORDKEEPING TIME

Instrument	Respondent	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Medical Assessment Form completed by a medical professional.	Care Provider Program Staff.	500	537	0.33	265,815	88,605
Medical Assessment form not completed by a medical professional (information obtained via health records).		500	100	0.17	25,500	8,500
Dental Assessment Form ...		500	32	0.17	8,160	2,720

Estimated Total Annual Burden Hours: 99,825.

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: 6 U.S.C. 279: Exhibit 1, part A.2 of the Flores Settlement Agreement (*Jenny Lisette Flores, et al.,* v. *Janet Reno, Attorney General of the United States, et al.,* Case No. CV 85–4544–RJK [C.D. Cal. 1996])

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–11626 Filed 5–31–23; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity: Strengthening Child Welfare Systems To Achieve Expected Child and Family Outcomes Cross-Site Evaluation (New Collection)

AGENCY: Children's Bureau, Administration for Children and Families, United States Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Children's Bureau, Administration for Children and Families (ACF), Department of Health and Human Services, is proposing to collect data for a new process and outcome study, Strengthening Child Welfare Systems to Achieve Expected Child and Family Outcomes (SCWS).

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The SCWS study will collect information to understand (1) implementation processes and the impact of grant interventions and (2) examine whether and the degree to which grant recipients were able to address common Child and Family Services Reviews (CFSR) outcomes. Proposed data sources for this effort include one survey and one focus group. The survey will gather information to understand the factors that supported or hindered implementation, as well as assess collaboration efforts and the intended impact of grant interventions. The focus groups will gather information to understand implementation of SCWS strategies and interventions, successes and challenges, and the perceived effect of the strategies on short and long-term child welfare outcomes, with specific attention to CFSR outcomes related to permanency.

Respondents: Respondents will include grant recipient staff, evaluators, and community partners.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
SCWS web-based survey	60	1	0.5	30	10
SCWS focus group	30	1	1.5	45	15

Estimated Total Annual Burden Hours: 25.

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: Statutory Authority Title II, Section 203(b)(4) of the Child Abuse Prevention and Treatment and Adoption Reform Act of 1978 (42 U.S.C. 5113(b)(4)).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–11634 Filed 5–31–23; 8:45 am]

BILLING CODE 4184–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0742]

Human Cells, Tissues, and Cellular and Tissue-Based Product Establishments That Are Improperly Registered in the Electronic Human Cell and Tissue Establishment Registration System Due to Lack of Annual Registration Update; Action Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of intent.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to begin inactivating the registration of establishments that manufacture human cells, tissues, or cellular or tissue-based products (HCT/Ps) that have not updated their registration during the annual update period, in accordance with FDA regulations, in the electronic human cell and tissue establishment registration system (eHCTERS). FDA regulations require establishments that manufacture certain HCT/Ps to update their establishment registration annually. These regulations also require establishments to amend their registration within 30 calendar days of certain changes.

DATES: This notice is applicable August 30, 2023.

FOR FURTHER INFORMATION CONTACT: Andrew C. Harvan, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

HCT/Ps are defined in § 1271.3(d) (21 CFR 1271.3(d)) as articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. FDA has a tiered, risk-based approach to the regulation of HCT/Ps. If all of the criteria in 21 CFR 1271.10(a) are met, and none of the exceptions in § 1271.15 (21 CFR 1271.15) apply, then the HCT/P is regulated solely under section 361 of the PHS Act (42 U.S.C. 264) and the regulations in part 1271 (21 CFR part 1271) (361 HCT/P), and FDA's premarket review and approval are not required.

Establishments that manufacture 361 HCT/Ps are required to register and list their HCT/Ps with FDA's Center for Biologics Evaluation and Research (CBER) using the electronic registration and listing system (§§ 1271.1(b), 1271.21, and 1271.22 (21 CFR 1271.1(b), 1271.21, and 1271.22)).[1] [2] Under § 1271.3(b), establishment ''means a place of business under one management, at one general physical location, that engages in the manufacture of [HCT/Ps].'' This includes ''any individual, partnership, corporation, association, or other legal entity engaged in the manufacture of [HCT/Ps] . . . [and includes] [f]acilities that engage in contract manufacturing services . . . .'' Under § 1271.3(e), ''manufacture means, but is not limited to, any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor.''

Pursuant to § 1271.21, establishments that manufacture 361 HCT/Ps must register with FDA and submit a list of every HCT/P that they manufacture within 5 days after beginning operations. Establishments are required to update their registration annually each December. Establishments are also required to update their HCT/P list when changes occur. Such new information must be submitted at the time of change, or each June or December, whichever month occurs first. An establishment may accomplish its required annual registration update in conjunction with updating its HCT/P list.

In addition, under 21 CFR 1271.26, if the ownership or location of the

[1] An establishment that meets any of the exceptions in § 1271.15 is not required to register or comply with other requirements in part 1271.

[2] Manufacturers of HCT/Ps that are regulated as drugs, devices, and/or biological products under section 351 of the PHS Act (42 U.S.C. 262) and/or the Federal Food, Drug, and Cosmetic Act and applicable regulations, must register and list their products in accordance with part 207 or part 807 (21 CFR part 207 or part 807), as applicable (§ 1271.1(b)(2)). FDA does not require establishments that manufacture HCT/Ps regulated as drugs, devices, and/or biological products that are only for use in research under an investigational new drug application (IND) (21 CFR part 312) or an investigational device exemption (IDE) (21 CFR part 812) to register and list those HCT/Ps in accordance with part 207 or part 807 if they do not engage in other activities that would require them to register (21 CFR 207.13(e), 807.65(f), and 812.1).