establishment changes or if there is a change in the establishment's U.S. agent's name, address, telephone number, or email address, then establishments must also amend their registration within 30 calendar days. Of note, the regulations make clear that FDA's ''acceptance of an establishment registration and HCT/P listing form does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA'' (21 CFR 1271.27(b)).

Registration is performed using CBER's eHCTERS. Establishments electronically submit required registration and HCT/P listing information, as well as updates to such information, through their eHCTERS account.[3] The public can access eHCTERS to search and review tissue establishment registration information (registered, inactive, and pre-registered establishments) through the eHCTERS Public Query Application.

Complete, accurate, and up-to-date establishment registration and HCT/P listing information is essential to FDA's mission. If registration and listing information is outdated or otherwise unreliable, the integrity of the HCT/P registration and listing database is compromised. Registration information assists FDA in identifying industry participants and the scope of HCT/Ps manufactured. This assists FDA in more efficiently monitoring industry and providing new information including guidances, policies, and requirements. Establishment registration information also assists FDA in reacting swiftly to newly discovered or understood risks by enabling FDA to quickly alert industry of our concerns and, when appropriate, to conduct establishment inspections. Without this information, FDA would not be able to effectively monitor compliance under FDA's risk-based surveillance inspection program.

Establishment registration and HCT/P listing information is also widely used outside of FDA for various purposes. The public uses the Public Query Application of eHCTERS to search for and locate HCT/P establishments. For example, certain voluntary healthcare accreditation organizations require hospitals or surgical centers to annually confirm that their tissue suppliers are registered with FDA. Therefore, inclusion of inaccurate or outdated information in eHCTERS can negatively affect public health.

II. Circumstances Under Which HCT/P Registration and Listing Information Becomes Inaccurate or Outdated

Establishments that manufacture HCT/Ps are required to update their registration annually in December, even if there are no changes or updates to their information (§ 1271.21). Every year, many HCT/P establishments fail to update their registration information during the annual update period. In recent years, 390 of 2671, 379 of 2361, and 319 of 2431 registered domestic and foreign establishments failed to submit their annual registration for 2019, 2020, and 2021, respectively. Some of the establishments have not submitted their annual update for more than 2 years.

After the annual registration period ends, CBER generates a list of establishments that have failed to submit their annual registration update. From this list, FDA attempts to follow up with each of these establishments to rectify their registration status. However, for a variety of reasons, such as outdated contact information, FDA is not able to contact some of these establishments. The follow-up process, including sending a reminder email and contact by phone, requires considerable additional time and FDA staff resources.

When establishments fail to update their registration information in eHCTERS, they are improperly registered in eHCTERS and improperly displayed in the Public Query Application as ''Registered''. Not only does this inaccurate and outdated information compromise the integrity of eHCTERS, it also hinders the public's ability to rely on establishment registration information.

III. FDA's Intended Response

To address the above registration and listing problems, FDA is encouraging establishments that are required to register under part 1271 to review their current registration to ensure its accuracy. Any registrations that are outdated should be updated as soon as possible. Establishments are required to annually update their registration pursuant to FDA regulations. Establishments who do not submit their annual registration are in violation of the regulations at part 1271.

Ninety days after publication of this notice, and every January thereafter, FDA will inactivate an HCT/P establishment's registration when the establishment fails to submit their annual registration update during the previous annual update period between November 15 to December 31. FDA will no longer attempt to follow up with establishments to rectify their registration status. The eHCTERS Public Query Application will display the establishment registration status as ''inactive'' and include the last annual registration year. Email notification of the inactivation will be sent to the reporting official of the establishment, and the reporting official may access the establishment's account in eHCTERS to change or update its registration. If the email notifying the establishment of the change in registration status to ''inactive'' is undeliverable, FDA will call the phone number of the establishment to provide notification.

If an establishment changes or updates its registration in eHCTERS after its registration has been inactivated due to failure to annually update registration information, the eHCTERS Public Query Application will display the establishment's status as ''Registered'' and the last annual registration year will be updated to the current year.

IV. Resources Available To Assist With Updating Registration and HCT/P Listings

Access to part 1271 is available at: *https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271?toc=1.* The instructions for using eHCTERS to complete HCT/P establishment registration and HCT/P listing and submitting the annual registration updates, as well as information on the eHCTERS Public Query Application, are available at: *https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/tissue-establishment-registration.* Questions concerning registration can be emailed to *tissuereg@fda.hhs.gov.*

Dated: May 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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BILLING CODE 4164–01–P

[3] Electronic submission of HCT/P establishment and product listing information may be waived in certain circumstances as described in 21 CFR 1271.23. Submission of a request for a waiver does not excuse timely compliance with registration and listing requirements.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Early Hearing Detection and Intervention (EHDI) Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of a HRSA-initiated competitive supplement for the EHDI Program.

SUMMARY: HRSA will provide supplemental award funds for up to 20 Early Hearing Detection and Intervention Program recipients of $75,000 each with a period of performance of 12 months to develop the necessary partnerships, assessments, evaluations, and other activities at the state and local levels to ensure that all children identified as deaf or hard of hearing (DHH) and their families receive the services they need to meet language acquisition and other developmental milestones by age 3.

FOR FURTHER INFORMATION CONTACT: Dana Simms, Project Officer, *dsimms@hrsa.gov* or 301–443–1623.

SUPPLEMENTARY INFORMATION:

Intended Recipient(s) of the Award: Up to 20 EHDI grantees of those listed in Table 1 who demonstrate readiness as articulated in review criteria on methodology, work plan, and budget to address language acquisition and other developmental milestones at age 3 for children identified as DHH.

Amount of Competitive Awards: Up to 20 awards at $75,000 ($1.5 million total).

Project Period: April 1, 2023–March 31, 2024.

Assistance Listing (CFDA) Number: 93.251.

Award Instrument: Supplement.

Authority: Public Health Service Act, Title III, Section 399M(a) (42 U.S.C. 280g–1(a)).

Purpose/Justification: The Consolidated Appropriations Act, 2023 (Pub. L. 117–328) provided HRSA's Maternal and Child Health Bureau with an additional $1 million for the EHDI program. The EHDI program currently funds 59 states and territories to support comprehensive systems of care so families with newborns, infants, and young children up to 3 years of age receive appropriate and timely services including screening, diagnosis, and early intervention. When children are identified as DHH early and they are provided with timely and appropriate intervention services, they have better vocabulary development, expressive language, and social-emotional development than children identified later. EHDI programs will use this supplemental support for 1 year to develop the necessary partnerships, assessments, evaluations, and other activities at the state and local levels to ensure that all children identified as DHH and their families receive the services they need to meet language acquisition and other developmental milestones by age 3. By September 2023, HRSA's Maternal and Child Health Bureau intends to provide a 1-year supplement for $75,000 for up to 20 existing grantees.

TABLE 1—CURRENT EHDI RECIPIENTS

Grant #	Award recipient name	State/territory
H61MC00015	Alaska Department of Health and Social Services	AK
H61MC00054	Alabama State Department of Public Health	AL
H61MC00076	Arkansas Department of Health	AR
H61MC33903	Department of Health American Samoa	AS
H61MC30765	EAR Foundation of Arizona	AZ
H61MC33904	NorCal for Deaf and Hard of Hearing	CA
H61MC33905	State of Colorado Department of Human Services	CO
H61MC00088	State of Connecticut	CT
H61MC00060	District of Columbia Department of Health	DC
H61MC23639	Delaware Department of Health & Social Services	DE
H61MC00086	Florida State Department of Health	FL
H61MC10346	Federated States of Micronesia	FM
H61MC22706	Georgia Department of Public Health	GA
H61MC24883	University of Guam	GU
H61MC00038	State of Hawaii Department of Health	HI
H61MC24884	University of Hawaii Systems	HI
H61MC26835	Iowa Department of Public Health	IA
H61MC00010	Idaho State Department of Health and Welfare	ID
H61MC04498	The Illinois Department of Health	IL
H61MC23640	Indiana State Department of Health	IN
H61MC00049	Kansas State Department of Health and Environment	KS
H61MC00033	Community For Children with Special Healthcare Needs	KY
H61MC00014	Louisiana State Department of Health and Hospitals	LA
H61MC00002	Massachusetts Department of Public Health	MA
H61MC00081	Maryland Department of Health and Mental Hygiene	MD
H61MC30766	Maine Educational Center for the Deaf & Hard of Hearing	ME
H61MC00056	Michigan Department of Community Health	MI
H61MC00035	Minnesota Department of Health	MN
H61MC00052	Mississippi State Department of Health	MS
H61MC00071	Missouri Department of Health	MO
H61MC30523	Commonwealth Healthcare Corporation	MP
H61MC00053	Montana State Department of Public Health and Human Services	MT
H61MC00043	North Carolina Department of Health & Human Services	NC
H61MC00028	Minot State University	ND
H61MC00065	Nebraska State Department of Health	NE
H61MC00034	New Hampshire Department of Health	NH
H61MC04397	New Mexico State Department of Health	NM
H61MC23641	New Jersey Department of Health and Senior Services	NJ
H61MC25010	Health and Human Services/Nevada Department of Health	NV
H61MC00005	Health Research Inc.	NY
H61MC00029	State of Ohio Department of Health	OH
H61MC00051	Oklahoma State Department of Health	OK
H61MC00057	Oregon State Department of Human Services	OR
H61MC24882	Commonwealth of Pennsylvania	PA
H61MC00050	Puerto Rico Department of Health	PR

TABLE 1—CURRENT EHDI RECIPIENTS—Continued

Grant #	Award recipient name	State/territory
H61MC05788	Republic of Palau	PW
H61MC00009	State of Rhode Island Department of Health	RI
H61MC00040	State of South Carolina	SC
H61MC33906	University of South Dakota	SD
H61MC00066	Tennessee State Department of Health	TN
H61MC26836	Texas Department of State Health Services	TX
H61MC00042	Utah Department of Health	UT
H61MC00046	Virginia State Department of Health	VA
H61MC23642	U.S. Virgin Islands Department of Health	VI
H61MC09029	Vermont State Agency for Human Services	VT
H61MC00084	Washington State Department of Health	WA
H61MC00024	Wisconsin Department of Health	WI
H61MC23643	West Virginia Department of Health and Human Resources	WV
H61MC00075	Wyoming State Department of Health	WY

Carole Johnson,

Administrator.

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BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Ryan White HIV/AIDS Program Part F Dental Services Report, OMB No. 0915–0151—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than July 3, 2023.

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 Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Ryan White HIV/AIDS Program Part F Dental Services Report, OMB No. 0915–0151—Extension.

Abstract: The Dental Reimbursement Program (DRP) and the Community Based Dental Partnership Program (CBDPP) under Part F of the Ryan White HIV/AIDS Program (RWHAP) offer funding to accredited dental education programs to support the education and training of oral health providers in HIV oral health care and reimbursement for the provision of oral health services for people eligible for the RWHAP. Institutions eligible for RWHAP DRP and CBDPP are accredited schools of dentistry and other accredited dental education programs, such as dental hygiene programs or those sponsored by a school of dentistry, a hospital, or a public or private institution that offers postdoctoral training in the specialties of dentistry, advanced education in general dentistry, or a dental general practice residency. The RWHAP DRP Application for the Notice of Funding Opportunity includes the Dental Services Report (DSR) that applicants use to apply for funding of non-reimbursed costs incurred in providing oral health care to patients with HIV and to report annual program data. Awards are authorized under section 2692(b) of the Public Health Service Act (42 U.S.C. 300ff–111(b)). The form is also used by CBDPP recipients to report on services rendered, patients served, and partnerships as an annual data report. The DSR collects data on program information, client demographics, oral health services, funding, and training. It also requests applicants to provide narrative descriptions of their services and facilities, as well as their linkages and how they collaborate with community-based providers of oral health services.

Beginning with the 2022 DSR submission, the DSR website provided RWHAP DRP applicants and RWHAP CBDPP recipients an easily accessible and secure location to enter and submit their aggregate DSR data annually. The web-based platform is accessible by all users and allows users to easily navigate the site and enter their data. Users can see their report submission status and will no longer email their completed dataset to HRSA. The implementation of the DSR website has contributed to the overall decrease in burden hours. HRSA proposes two additions to the DSR data reporting tool. First, HRSA proposes adding an additional response option to the HIV/AIDS Status question to record clients whose HIV status is indeterminate. Second, HRSA proposes adding a question that will identify specific populations such as LGBTQI, urban/suburban/rural persons, homeless persons, persons with substance use disorder, migrant or seasonal workers, incarcerated/paroled persons, and/or runaway youth, who were specifically prioritized to receive services through community-based partnership programs.

A 60-day notice was published in the **Federal Register** on March 8, 2023 (Volume 88, No. 45, pages 14375–76). There were no public comments in response to the notice.

Need and Proposed Use of the Information: The primary purpose of collecting this information annually is to verify applicant eligibility and determine reimbursement amounts for DRP applicants, as well as to document the program accomplishments of