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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–25–1391; Docket No. CDC–2025–0156]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Enhancing Data-driven Disease Detection in Newborns (ED3N). This national newborn screening (NBS) data platform serves as a secure, central, and national data sharing resource for the U.S. state and territorial NBS community.

DATES: CDC must receive written comments on or before September 16, 2025.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2025–0156 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Enhancing Data-Driven Disease Detection in Newborns (ED3N) (OMB Control No. 0920–1391, Exp. 4/30/2026)—Revision—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Newborn Screening and Molecular Biology Branch (NSMBB), in the National Center for Environmental Health (NCEH) Division of Laboratory Science (DLS), has the only laboratory in the world devoted to ensuring the accuracy of newborn screening (NBS) tests in every state and more than 78 countries. NSMBB supports NBS programs by conducting research, developing methods, and performing analyses by using complex, state-of-the-art molecular and biochemical techniques for identifying risk factors for diseases of public health importance.

Both NSMBB and state NBS programs are experiencing increased data analytic challenges associated with continued expansion of the number of newborn screening diseases, increased complexity of disease detection, and difficulties in correlating disease markers with disease risk. Further, the addition of late-onset diseases to NBS panels necessitates a better way to routinely capture clinical information and outcomes so that NBS programs can fully appreciate the spectrum of disease they are detecting.

The NSMBB is requesting a three-year Paperwork Reduction Act (PRA) Extension for Enhancing Data-driven Disease Detection in Newborns (ED3N), the NBS data platform, that will address these analytic and post-analytic challenges and promote sharing of molecular, biochemical, and clinical information amongst NBS partners. The information shared will help NSMBB and newborn screening partners be better equipped to assess disease risk and will help harmonize approaches for disease detection in newborns. Given the rarity of newborn screening diseases, it is imperative that data be collected and analyzed at a national level in order to glean useful insights and to analyze trends. The NSMBB is best suited to oversee this work given its role in providing technical assistance to NBS programs nationally.

Numerous studies along with presentations by NBS programs suggest that gaps in programmatic resources and expertise are hampering the ability to perform more complex data analytics resulting in low positive predictive values for a number of conditions (which subsequently results in higher false positive and negative rates and downstream burden to families and the medical system). Smaller-scale work on the use of post-analytical tools such as machine learning algorithms have shown that incorporation of these elements into newborn screening can improve detection rates, while reducing false positives. These studies, however, have been limited to single sites and have not been integrated into the daily workflow of high-throughput NBS programs. Without this project, NBS

programs will continue to be unable to keep up with the increasing complexity and future demands of screening, perpetuating inequities in screening across the nation.

The estimated annualized burden hours were determined as follows. There are 53 domestic NBS programs in the U.S. A ''respondent'' refers to a single NBS program. Given that data submission will ultimately be accomplished through automatic electronic data transfer, each respondent's burden hours were split into two estimates: (1) the one-time need to set-up, test, and implement the electronic data transfer mechanism; and (2) the ongoing automatic electronic data transfer occurring after initial set-up. Initial set-up time burden was estimated based on analysis of similar data transfer projects embarked upon by NBS programs as well as brief discussions with NBS Program Laboratory Information Management System vendors. The one-time burden to set up the data transfer interface was estimated to be 40 hours total, annualized to 14 hours per year. Ongoing daily data submission burden for NBS programs was estimated assuming one minute per automatic transfer thereafter. CDC has estimated the total annualized burden for this project to be 1,064 hours per year.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)
Newborn Screening Programs	Set-up and initial submission of ED3N Data Elements.	53	1	14	742
	Ongoing transfer of ED3N Data Elements	53	364	1/60	322
Total		53			1,064

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Telehealth Resource Center Performance Measurement Tool, OMB No. 0915–0361—Revision

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

ACTION: Notice.

SUMMARY: In compliance with 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 August 18, 2025.

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: Telehealth Resource Center Performance Measurement Tool, OMB No. 0915–0361—Revision.

Abstract: HRSA requests a revision of its approved Telehealth Resource Center (TRC) Performance Measurement Tool and renewal of the previously approved performance measures. TRCs deliver telehealth technical assistance under cooperative agreements awarded by HRSA's Office for the Advancement of Telehealth, as authorized by section 330I(d)(2) of the Public Health Service Act (42 U.S.C. 254c–14(d)(2)). There are two types of HRSA TRC programs:

1. Two National TRC Programs focus on policy and technology.

2. Twelve Regional TRC Programs host activities and provide resources to rural and underserved areas.

HRSA TRCs

- Provide training and support,
- Publicize information and research findings,
- Support collaboration and partnerships,
- Promote effective partnerships, and
- Promote the use of telehealth by providing health care information and education to the public and medical specialists.

TRCs share expertise through individual consults, training, webinars, conference presentations, and the web. HRSA collects information using the TRC Performance Measurement Tool.

HRSA seeks to revise its approved information collection because the electronic system for submitting information to HRSA has changed from the Performance Improvement Management System to Data Collection Platform as a Service (DCP). Although the electronic system has changed, the information collected using the TRC Performance Measurement Tool has not changed and HRSA's burden estimate remains the same.

A 60-day notice published in the **Federal Register** on May 15, 2025, vol. 90, No. 93; pp. 20677–79. There were no public comments.

Need and Proposed Use of the Information: To evaluate existing programs, recipients of the National and Regional TRC cooperative agreements submit data through HRSA's DCP. The data are used to measure the effectiveness of technical assistance. There is one data reporting period each year; during this reporting period, data are reported for the previous 12 months of activity. TRCs have approximately 6 weeks to enter their data into the DCP system during each annual reporting