DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-23-22BC]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "Enhancing Data-driven Disease Detection in Newborns (ED3N)" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on December 6, 2021 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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 submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Enhancing Data-driven Disease Detection in Newborns (ED3N) – New - 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) clearance for Enhancing Data-driven Disease Detection in Newborns (ED3N), a new national 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 will better equip NSMBB and newborn screening partners 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.

There are 53 domestic NBS programs in the United States. 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. For purposes of annualizing this component of burden over the three-year period of this request, the 53 respondents are represented as 18 respondents in the table below (53/3 = 17.67, rounded to 18). Ongoing daily data submission burden was estimated assuming automatic transfer thereafter, 365 days per year. The estimated burden per response is one minute.

CDC requests OMB approval for an estimated 1,042 annualized burden hours. There are no costs to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses	Average Burden per

			per Respondent	Response (in hr)
Newborn Screening Programs	Set-up of ED3N Data Elements	18	1	40
	Ongoing transfer of ED3N Data Elements	53	365	1/60

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