stimuli and one on cigarette-focused stimuli) will be fielded as appropriate, but not within the same month.

In support of the provisions of the Tobacco Control Act that require FDA to protect the public health and to reduce tobacco use by minors, FDA requests OMB approval to collect information to evaluate CTP's public education campaign ''The Real Cost'' through the MIA.

In the **Federal Register** of April 27, 2023 (88 FR 25660), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent/activity	Number of respondents	Number of responses per respondent	Total responses	Average burden per response	Total hours
Parent Screener	2,338,560	1	2,338,560	0.05 (3 minutes)	116,928
Parent Permission	1,753,920	1	1,753,920	0.05 (3 minutes)	87,696
Invitation Emails (Respondents ages 18–20)	54,096	1	54,096	0.02 (1 minute)	1,082
Youth Assent	27,936	1	27,936	0.05 (3 minutes)	1,397
Young Adult Consent	20,064	1	20,064	0.05 (3 minutes)	1,003
Online Survey	48,000	1	48,000	0.42 (25 minutes)	20,160
Reminder Emails	48,000	1	48,000	0.20 (12 minutes)	9,600
Total					237,866

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Data collection for the MIA will consist of administering a monthly survey to participants ages 12–20 over the course of 2 years (24 months). We expect the screening process (3 minutes per response) to yield an approximate 2.3 to 1 ratio of eligible participants. We will need to screen approximately 97,440 potential parents each month (resulting in 2,338,560 screeners) over the study period. Since the eligible age for data collection is 12 to 20 years old, we intend to screen parents of eligible youth and young adults. Parents of the youth participants determined to be eligible through the screener will provide parent permission (3 minutes per response). We estimate that 1,753,920 of the parents who complete the screener will provide their permission for their youth to complete the online survey (approximately 75 percent of the 2,338,560 screened). In addition to recruiting respondents through parents, we will send direct invitations to young adult panel members (18 to 20 years old). We anticipate that 50 percent of young adults will agree to participate. We will send 508 direct invitations a month to young adult panel members (18 to 20 years old). Eligible youth (1,753,920) will provide their assent (3 minutes per response) to participate in the online survey (25 minutes per response). Participants who are 18 to 20 years old (19 to 20 years old in Alabama and Nebraska in accordance with state law) will provide their consent (3 minutes per response) to participate in the online survey. We estimate that approximately 42 percent of the 48,000 completed surveys will come from young adults aged 18 to 20 (aged 19 to 20 in Alabama and Nebraska).

Over the course of the study period, we intend to survey approximately 2,000 teens ages 12–20 per month for 24 months. From completed screeners, we estimate that we will obtain data from approximately 27,936 youth and 20,064 young adults. This will give us a total of 48,000 participants for the study. The survey will be repeated with a new cross-sectional sample approximately every month over a period of 24 months; however, some participants will complete more than one wave. These 48,000 respondents will receive an invitation email with a link to take the survey (4 minutes), 6 reminder emails (3 minutes each), and a thank you email (3 minutes) upon completion of the study for a total of 25 minutes for respondents to read and respond to the emails.

Several changes have been made to this information collection request since the 60-day notice was published in the **Federal Register**. These changes include (a) editing to clarify that the ad campaign is intended for ''teens'' not just ''youth;'' (b) removing the focus on video ads since the campaign may use other forms of communication to deliver its message and replacing the term ''ad'' with ''stimuli;'' (c) removing the youth screener from the burden table because parents determine the eligibility of their youth aged 12–17 (18–20 in Alabama and Nebraska in accordance with state law); (d) removing the young adult screener from the burden table, which will not be needed because young adult panel members (18–20 years old) will only receive an email invitation to complete the survey; (e) updating the burden table to reflect that we will send direct invitations to young adult panel members (18–20 years old); (f) updating the permission, assent, and consents because of updated information on the expected sample breakdown from the sample vendor for the distribution of the sample who are 12–17 years old and 18–20 years old; and (g) removing the thank you email since that will not be a part of the data collection procedures. In addition to the implementation evaluation described above, we will also assess perceptions to proposed stimuli and potential unintended consequences in order to inform the development of future messaging.

Dated: February 28, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–04526 Filed 3–4–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Request for Information: Nomination and Evidence-Based Review Process of the Advisory Committee on Heritable Disorders in Newborns and Children

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

ACTION: Notice of request for public comment.

SUMMARY: At the request of the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or

Committee), HRSA is requesting input from the public on the process used by the Committee for nomination and evidence-based review of conditions that are considered for inclusion in the Recommended Uniform Screening Panel (RUSP). As an entity that advises the Secretary of Health and Human Services (Secretary) based on evidence-based information, ACHDNC periodically considers and evaluates its processes. During the November 2023 meeting, ACHDNC hosted listening sessions to learn more from stakeholders regarding their views on the process used by ACHDNC for nomination and evidence-based review of conditions. In support of this work, HRSA is seeking public input on a series of questions that will help inform the nomination and review processes.

DATES: Comments on this FRN should be received no later than April 4, 2024.

ADDRESSES: Responses must be submitted electronically as email attachments to CDR Leticia Manning, MPH, ACHDNC's Designated Federal Officer, at: *ACHDNC@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: CDR Leticia Manning, MPH, Designated Federal Officer, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–8335; or *ACHDNC@hrsa.gov.* A copy of the ACHDNC charter may be obtained by accessing the ACHDNC website at: *https://www.hrsa.gov/advisory-committees/heritable-disorders.*

SUPPLEMENTARY INFORMATION: ACHDNC was established in 2003 and provides advice and recommendations to the Secretary on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening on the RUSP, following adoption by the Secretary, are evidence-informed preventive health services provided for in comprehensive guidelines supported by HRSA pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13), for which certain health insurance plans and issuers are required to provide coverage without cost-sharing. The ACHDNC meets four times each calendar year or at the discretion of the Designated Federal Officer in consultation with the Chair.

Responses

HRSA is seeking responses on the following questions. Responses to all questions are voluntary, and a response to each question is not required.

Nomination Process: The current nomination process can be found here: *https://www.hrsa.gov/advisory-committees/heritable-disorders/condition-nomination.* The Committee has already received feedback from newborn screening stakeholders on the current nomination process, and based on this feedback, the Committee is requesting that HRSA publish this notice to obtain additional public feedback on the proposed revisions to the questions addressed within the nomination package.

Please provide feedback in response to the questions on the proposed elements below (*i.e.,* the condition, newborn screening, and benefits and harms of newborn screening), including:

(1) Whether these questions add clarity to what is required for a condition nomination package?

(2) Whether appropriate language is used to describe the required information for each section?

(3) Whether this question-based format makes clearer the requirements for a nomination? If not, please propose edits and/or changes to what is provided.

Please cite any available information that you may have to support your responses.

Section I: The Condition

(1) What is the specific condition to be screened for (''target condition'') and how is it defined?

(2) How is the condition diagnosed as part of usual clinical care? Why is the current clinical diagnostic approach inadequate?

(3) What is the reported birth prevalence of the condition in the United States (or comparable newborn population)? Is the condition more common in certain populations?

(4) Describe the severity of the condition when detected as part of usual clinical care.

Section II: Newborn Screening

(1) What testing approach(es) are you suggesting for newborn screening? Please be specific regarding the approach to screening (*e.g.,* dried-blood spot, point-of-care screening, what specimen or test). Is there one or more tiers of testing that should occur before a diagnostic referral to a clinical specialist?

(2) How is the condition diagnosed after an at-risk child is identified through newborn screening? (*i.e.,* How does a clinical specialist confirm that an infant has the condition after referral from the newborn screening program?)

(3) What other conditions could be identified through newborn screening for the target condition as nominated? This includes phenotypes of the target condition that are *not* being nominated for newborn screening (*e.g.,* late-onset, mild variants). Will screening for the target condition identify carriers?

(4) What examples are there of screening and diagnosis for the condition at a prospective population level (*e.g.,* through state newborn screening (NBS) program or pilot studies)? Has at least one case of the condition been identified, diagnosed, and treated through a prospective population-based approach?

(5) Based on at least one example of a prospective population level study from question #4, please describe the epidemiologic elements a–e below. (Include a peer-reviewed study, if available.):

(a) The birth prevalence of the target condition.

(b) The birth prevalence of the *other* conditions that could be identified by screening.

(c) The percentage of newborns *with* the target condition who had a positive screen (*sensitivity* of NBS test).

(d) The percentage of newborns with one of the *other conditions* who were identified through newborn screening with the target condition.

(e) The percentage of newborns *without* the target condition who had a negative screen (*specificity* of NBS test).

Section III: Benefits and Harms of Newborn Screening

(1) What is the expected *benefit* to infants and/or families for detection of the condition through newborn screening compared to clinical care identification?

(2) What is the expected *harm* to infants and/or families for detection of the condition through newborn screening compared to clinical care identification?

(3) Are there other benefits or harms that may result from implementing a state newborn screening program? (*e.g.,* false positive or negative results, infants identified with other conditions, or opportunity costs to a state public health system)

(4) What treatment and management protocols are available for newborns identified with the condition through newborn screening?

(5) What plan for longitudinal follow-up of newborns identified through newborn screening is available? For example, will there be a patient registry available for use by clinical providers or by individuals/families? For how many years would infants with the condition be followed?

Evidence-based Review Process: The current criteria for ACHDNC to recommend inclusion of a condition on the RUSP to the Secretary is based primarily on peer-reviewed evidence regarding the certainty that benefits of universal screening outweigh harms (''net benefit''). These criteria have been largely applied to focus on the benefits and harms to the individual child, with much less consideration of benefits and harms to the family, states, or to the public health system. Financial and opportunity costs have received less attention by ACHDNC, in part because of the lack of published evidence regarding such topics.

Below is an example of what published evidence should be considered by the Committee when conducting a condition evidence review. The Committee requests feedback regarding the example below.

When weighing certainty and net benefit of screening for a condition, the Committee should consider the full range of relevant, published, peer-reviewed evidence. Although such evidence in relation to benefits and harms to the individual child remain paramount, the Committee should also consider benefits and harms to the family and to society at large, including disproportionate impacts or disparities related to specific conditions or screening. For example, the Committee could consider evidence demonstrating benefits for the family regarding future planning (*e.g.,* finances, geographic proximity to services, home design, etc.), earlier access to early intervention programs, or opportunity costs to the public health system. Ideally, potential harms and benefits should be supported by evidence directly relevant to the condition under review. When such evidence is lacking, Committee members could consider peer-reviewed evidence from other disorders to the extent that such evidence is considered potentially relevant to the condition under consideration.

Special Note to Commenters

The information obtained through this request for information (RFI) may help inform ACHDNC processes. Per the ACHDNC Charter, the Committee has the responsibility to decide the processes for nomination, evidence review, and making recommendations regarding the RUSP. How Committee members ultimately vote on recommending a condition for inclusion on the RUSP will continue to reflect their judgment on the certainty of net benefit to the entire population of infants born in the United States.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal, applications, proposal abstracts, or quotations. This RFI does not commit the U.S. government to contract for any supplies or services or make a grant or cooperative agreement award. Further, HRSA is not seeking proposals through this RFI and will not accept unsolicited proposals. HRSA will not respond to questions about the policy issues raised in this RFI. Responders are advised that the U.S. government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense.

Authority: ACHDNC is authorized by section 1111(g) of the Public Health Service Act, 42 U.S.C. 300b–10(g), and the Federal Advisory Committee Act, 5 U.S.C. chapter 10.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–04618 Filed 3–4–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0955–0018]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before April 4, 2024.

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.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 264–0041, or *PRA@HHS.GOV.* When submitting comments or requesting information, please include the document identifier 0955–0018–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program.

Type of Collection: Reinstatement without change.

OMB No: 0955–0018.

Abstract: The Department of Health and Human Services, Office of the Secretary, Office of the National Coordinator for Health IT Office of Policy, is requesting an approval by OMB for reinstatement without change which pertains to a records and information retention requirement found at 45 CFR 170.402(b)(1). The purpose and use of this records and information retention requirement is to verify, as necessary, health IT developer compliance with the ONC Health IT Certification Program (Program) requirements, including certification criteria and Conditions and Maintenance of Certification. Specifically, a health IT developer must, for a period of 10 years beginning from the date each of a developer's health IT is first certified under the Program, retain all records and information necessary that demonstrate initial and ongoing compliance with the requirements of the Program.