Background and Brief Description

In 2012, CDC's Office on Smoking and Health obtained OMB approval of a generic clearance to support the development and testing of tobacco-related health messages, including messages disseminated through multiple phases of a media campaign (Message Testing for Tobacco Communication Activities (MTTCA), OMB Control Number 0920–0910, expiration date 1/31/2015). In 2014, OSH obtained approval for a modification to the MTTCA clearance that granted a three-year extension and an increase in respondents and burden hours (MTTCA, OMB Control Number 0920–0910, expiration date 3/31/2018). CDC's authority to collect information for public health purposes is provided by the Public Health Service Act (41 U.S.C. 241) Section 301.

CDC has employed the MTTCA clearance to collect information about adult smokers' and nonsmokers' attitudes and perceptions, and to pretest draft messages and materials for clarity, salience, appeal, and persuasiveness. The MTTCA clearance has been used to obtain OMB approval for a variety of message testing activities, with particular emphasis on communications supporting CDC's National Tobacco Education Campaign (NTEC) called the *Tips from Former Smokers*® campaign. This national campaign is designed to increase public awareness of the health consequences of tobacco use and exposure to secondhand smoke. The MTTCA clearance has also supported formative research relating to the development of health messages that are not specifically associated with the national campaign.

Information collection modes under the MTTCA clearance that are supported include in-depth interviews; in-person focus groups; online focus groups; computer-assisted, in-person, or telephone interviews; and online surveys. Each project approved under the MTTCA framework is outlined in a project-specific Information Collection Request that describes its purpose and methodology. Messages developed from MTTCA data collection have been disseminated via multiple media channels including television, radio, print, out-of-home, and digital formats.

CDC requests OMB approval to extend the MTTCA clearance, without changes, for three years. No modification is requested for information collection activities, methodology, respondents, or burden from the existing generic clearance. The extension is needed to support CDC's planned information collections and to accommodate additional needs that CDC may identify during the next three years. For example, the MTTCA generic clearance may be used to facilitate the development of tobacco-related health communications of interest for CDC's collaborative efforts with other federal partners including, but not limited to, the Food and Drug Administration's Center for Tobacco Products. At this time, the respondents and burden outlined in the existing MTTCA clearance are expected to be sufficient to test tobacco related messages developed by CDC for the general US population and subpopulations of interest. The MTTCA clearance should not replace the need for additional generic clearance mechanisms of HHS and other federal partners that may need to test tobacco messages related to their campaigns and initiatives.

The existing MTTCA clearance was granted approval for a total of 132,648 respondents and 32,994 burden hours over a three-year period (annualized number of respondents of 44,216 and annualized burden hours to 10,998). To date, there have been 63,475 respondents and 11,737 burden hours used in this clearance, leaving a balance of 69,173 respondents and 21,257 burden hours (annualized number of respondents of 23,057 and annualized burden hours to 7,085 for each of the three years in the requested extension). CDC will continue to use the MTTCA information collection plan to develop and test messages and materials. Participation is voluntary and there are no costs to respondents, other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
General Public and Special Populations.	Screening	23,057	1	2/60	769
	Short Surveys/employment application (Online, Bulletin Board, etc.).	13,224	1	10/60	2,204
	Medium Surveys (Online)	9,833	1	25/60	4,097
Total		23,057			7,070

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–06392 Filed 3–29–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–18–18TH; Docket No. CDC–2018–0027]

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 proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled ''Assessment of a Preventive Service Program in the Context of a Zika

Virus Outbreak in Puerto Rico''. Data collected will be used to assess implementation of a patient-centered prevention program and associated outcomes.

DATES: CDC must receive written comments on or before May 29, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0027 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

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

Please note: Submit all comments through the Federal eRulemaking portal (*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 Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 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; and
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.
5. Assess information collection costs.

Proposed Project

Assessment of a Preventive Service Program in the Context of a Zika Virus Outbreak in Puerto Rico—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Puerto Rico has reported the highest number of Zika virus infections in the United States, including infections in pregnant women. Zika virus infection during pregnancy has been identified as a cause of microcephaly and other severe brain abnormalities, and has been linked to other problems such as miscarriage, stillbirth, defects of the eye, hearing deficits, limb abnormalities, and impaired growth. One strategy to prevent these devastating outcomes is to prevent unintended pregnancy among women at risk of Zika virus infection. To this end, an initiative was launched in April 2016 to train physicians at clinics across Puerto Rico to provide patient-centered services to women who chose to delay or avoid pregnancy during the Zika virus outbreak.

As part of the public health response to the Zika virus outbreak, CDC seeks to assess approaches to mitigating the effects of Zika virus infection and determine which approaches have utility. Previous assessment of the prevention program indicated high satisfaction of Z–CAN patients with program services. The specific objectives of this data collection are to assess: (1) Prevention strategy adherence among Z–CAN patients at approximately 18 months after receipt of program services; and (2) prevention strategy adherence, patient satisfaction, and unmet need for services among Z–CAN patients at approximately 30 months after receipt of program services. The practical utility of the collected information is to assess services delivered to women in Puerto Rico, monitor outcomes of interest, and determine potential for replication/adaptation in other jurisdictions similarly affected by the Zika virus or during other emergency responses.

For the information collection project, CDC plans to conduct online surveys with 1,600 patients approximately 18 and 30 months after receiving program services.

Participation in all data collection activities will be completely voluntary. CDC intends to request a two-year OMB approval to collect information. Total Annualized Burden Hours are estimated to be 259, and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Patients aged 18 years or older	Online surveys (18-month follow-up)	960	1	7/60	112
Patients aged 18 years or older who completed 18-month survey.	Online surveys (30-month follow-up)	660	1	10/60	110
Patients aged 18 years or older who did not complete 18-month survey.	Online surveys (30-month follow-up)	220	1	10/60	37
Total					259

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1697–N]

Medicare Program; Public Meeting on June 25, 2018 Regarding New and Reconsidered Clinical Diagnostic Laboratory Test Codes for the Clinical Laboratory Fee Schedule for Calendar Year 2019

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a public meeting to receive comments and recommendations (including accompanying data on which recommendations are based) from the public on the appropriate basis for establishing payment amounts for new or substantially revised Healthcare Common Procedure Coding System (HCPCS) codes being considered for Medicare payment under the clinical laboratory fee schedule (CLFS) for calendar year (CY) 2019. This meeting also provides a forum for those who submitted certain reconsideration requests regarding final determinations made last year on new test codes and for the public to provide comment on the requests.

The Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (Advisory Panel on CDLTs) will participate in this Annual Laboratory Public Meeting by gathering information and asking questions to presenters, and will hold its next public meeting on July 16 and 17, 2018. The public meeting for the Advisory Panel on CDLTs will focus on discussion of and recommendations for test codes presented during the June 25, 2018 Annual Laboratory Public Meeting. The Panel meeting also will address other CY 2019 CLFS issues that are designated in the Panel's charter and specified on the meeting agenda may also be discussed.

DATES:

Annual Laboratory Public Meeting Date: The meeting is scheduled for Monday, June 25, 2018 from 8:00 a.m. to 5:00 p.m., E.D.T.

Deadline for Registration of Presenters and Submission of Presentations: All presenters for the Annual Laboratory Public Meeting must register *and* submit their presentations electronically to our CLFS dedicated email box, *CLFS_Annual_Public_Meeting@cms.hhs.gov,* by June 11, 2018 at 5:00 p.m. E.D.T.

Deadline for Submitting Requests for Special Accommodations: Requests for special accommodations must be received no later than 5:00 p.m. E.D.T. on June 11, 2018.

Deadline for Submission of Written Comments Related to the Annual Laboratory Public Meeting: Written comments regarding the presentations must be received by July 9, 2018 at 5:00 p.m. E.D.T. (2 weeks after the meeting).

Publication of Proposed Determinations: We intend to publish our proposed determinations for new test codes and our preliminary determinations for reconsidered codes (as described later in this notice in section II. ''Format'') for CY 2019 by early September 2018.

Deadline for Submission of Written Comments Related to Proposed Determinations: Comments in response to the preliminary determinations will be due by early October 2018.

Where to Submit Written Comments: Interested parties should submit all written comments on presentations and preliminary determinations to the address specified in the **ADDRESSES** section of this notice or electronically to our CLFS dedicated email box, *CLFS_Annual_Public_Meeting@cms.hhs.gov* (the specific date for the publication of these determinations on the CMS website, as well as the deadline for submitting comments regarding these determinations, will be published on the CMS website).

ADDRESSES: The Annual Laboratory Public Meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services (CMS), Central Building, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

FOR FURTHER INFORMATION CONTACT: Glenn McGuirk, (410) 786–5723.

SUPPLEMENTARY INFORMATION:

I. Background

Section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) required the Secretary of the Department of Health and Human Services (the Secretary) to establish procedures for coding and payment determinations for new clinical diagnostic laboratory tests under Part B of title XVIII of the Social Security Act (the Act) that permit public consultation in a manner consistent with the procedures established for implementing coding modifications for International Classification of Diseases (ICD–9–CM) (now, ICD–10–CM). The procedures and clinical laboratory fee schedule (CLFS) public meeting announced in this notice for new tests are in accordance with the procedures published on November 23, 2001 in the **Federal Register** (66 FR 58743) to implement section 531(b) of BIPA.

Section 942(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) added section 1833(h)(8) of the Act. Section 1833(h)(8)(A) of the Act requires the Secretary to establish by regulation procedures for determining the basis for, and amount of, payment for any clinical diagnostic laboratory test for which a new or substantially revised Healthcare Common Procedure Coding System (HCPCS) code is assigned on or after January 1, 2005 (hereinafter referred to as ''new tests''). A code is considered to be substantially revised if there is a substantive change to the definition of the test or procedure to which the code applies (such as, a new analyte or a new methodology for measuring an existing analyte-specific test). (See section 1833(h)(8)(E)(ii) of the Act and 42 CFR 414.502).

Section 1833(h)(8)(B) of the Act sets forth the process for determining the basis for, and the amount of, payment for new tests. Pertinent to this notice, sections 1833(h)(8)(B)(i) and (ii) of the Act require the Secretary to make available to the public a list that includes any such test for which establishment of a payment amount is being considered for a year and, on the same day that the list is made available, causes to have published a notice in the **Federal Register** of a meeting to receive comments and recommendations (including accompanying data on which recommendations are based) from the public on the appropriate basis for establishing payment amounts for the tests on such list. This list of codes for which the establishment of a payment amount under the CLFS is being considered for CY 2019 will be posted on the CMS website concurrent with the publication of this notice and may be updated prior to the Annual Laboratory Public Meeting. The Annual Laboratory Public Meeting list of codes can be found on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/*. Section 1833(h)(8)(B)(iii) of the Act requires that we convene the public meeting not less