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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–18–18AVU; Docket No. CDC–2018–0081]

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 efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this 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 Outcomes Associated with the Preventive Health and Health Services Block Grant*”. This assessment will assess select cross-cutting outputs and outcomes of the Preventive Health and Health Services Block Grant and demonstrates the utility of the grant on a national level.

DATES: CDC must receive written comments on or before November 5, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0081 by any of the following methods:

- **Federal eRulemaking Portal:** *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–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 Jeffrey M. Zirger, 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 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 Outcomes Associated with the Preventive Health and Health Services Block Grant—New—Office for State, Tribal, Local and Territorial Support (OSTLTS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

For more than 35 years, the Preventive Health and Health Services Block Grant (PHHS Block Grant) has provided flexible funding for all 50 states, the District of Columbia, two American Indian tribes, five U.S. territories, and three freely associated states to address the unique public health needs of their jurisdictions in innovative and locally defined ways. First authorized by Congress in 1981 through the Public Health Service Act (Pub. L. 102–531), the fundamental and enduring purpose of the grant has been to provide grantees with flexibility and control to address their priority public health needs. In 1992, Congress amended the law to align PHHS Block Grant funding priorities with the 22 chapters specified in Healthy People (HP) 2000, a set of national objectives designed to guide health promotion and disease prevention efforts. Additional amendments included set-aside funds specifically dedicated to sex offense prevention and victim services, thus requiring grantees receiving this support to include related HP objectives and activities as part of their PHHS Block Grant-funded local programs.

CDC is establishing a comprehensive, standardized method to collect data to describe select outputs and outcomes and ensure the accountability of the PHHS Block Grant. The CDC PHHS Block Grant Measurement Framework is an innovative approach to assessing cross-cutting outputs and outcomes resulting from grantees' use of flexible grant funds. The framework defines four measures that enable CDC to standardize the collection of data on grantee achievements. The measures capture data on public health infrastructure improved (*i.e.*, information systems improved and quality improved—efficiency and effectiveness improvements achieved in programs, services, and operations), emerging public health needs addressed, and evidence-based public health interventions implemented.

The purpose of this information collection request (ICR) is to collect data that assess select cross-cutting outputs and outcomes of the grant (as defined by the framework measures) and that demonstrate the utility of the grant on a national level. This data collection will describe the outcomes of the PHHS Block Grant as a whole—not individual grantee activities or outcomes. Findings from this data collection will be used to: (1) Describe the outcomes and achievements of grantees' public health efforts and identify how the use of PHHS Block Grant funds contributed to

those results, and (2) help assess how the PHHS Block Grant advances work of the public health system and provides evidence to support future budgetary requests.

The respondent universe consists of 61 PHHS Block Grant coordinators, or

their designees, across 61 health departments (50 states, the District of Columbia, two tribes, five US territories, and three freely associated states). The assessment will be administered to PHHS Block Grant coordinators

electronically via a web-based questionnaire. A link to the assessment will be provided by email invitation. The survey will be completed once every two years. The total annualized estimated burden is 46 hours.

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)
PHHS Block Grant Coordinators, or Designees.	PHHS Block Grant Assessment	61	1	45/60	46
Total	46

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3130]

Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions.” This guidance document describes FDA’s current approach to considering uncertainty in making benefit-risk determinations to support certain FDA premarket decisions for medical devices—premarket approval applications (PMAs), De Novo requests, and humanitarian device exemption (HDE) applications. This guidance document elaborates on the consideration of uncertainty as part of our overarching approach to a benefit-risk based framework that is intended to assure

greater predictability, consistency, and efficiency through the application of least burdensome principles. This draft guidance also provides examples of how the principles for considering uncertainty could be applied in the context of clinical evidence and circumstances where greater uncertainty could be appropriate in premarket decisions, balanced by postmarket controls—PMAs for Breakthrough Devices and PMAs for devices for small patient populations. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by December 5, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you

do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2018–D–3130 for “Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions; Draft Guidance for Industry and Food and Drug Administration Staff.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The