

application and approval process for survey vendors who want to participate in collecting QHP enrollee experience data.

The QHP Enrollee Survey, which is based on the CAHPS® Health Plan Survey, will be used to (1) help consumers choose among competing health plans, (2) provide actionable information that the QHPs can use to improve performance, (3) provide information that regulatory and accreditation organizations can use to regulate and accredit plans, and (4) provide a longitudinal database for consumer research. CMS completed two rounds of developmental testing including 2014 psychometric testing and 2015 beta testing of the QHP Enrollee Survey. The psychometric testing helped determine psychometric properties and provided an initial measure of performance for Marketplaces and QHPs to use for quality improvement. Based on psychometric test results, CMS further refined the questionnaire and sampling design to conduct the 2015 beta test of the QHP Enrollee Survey. CMS previously obtained clearance for the 2016 and 2017 administrations of the QHP Enrollee Survey.

At this time, CMS is requesting to renew approval for the information collection related to the QHP Enrollee Experience Survey in 2018–2020. These activities are necessary to ensure that CMS fulfills legislative mandates established by section 1311(c)(4) of the Affordable Care Act to develop an “enrollee satisfaction survey system” and provide such information on Marketplace Web sites. CMS is also seeking approval to remove eight survey questions beginning with the 2018 survey administration. With the removal of these eight questions, the revised total estimated annual burden hours of national implementation of the QHP Enrollee Survey is 22,523 hours with 90,015 responses. The revised total annualized burden over three years for this requested information collection is 67,569 hours and the total average annualized number of responses is 270,045 responses. *Form Number:* CMS–10488 (OMB control number: 0938–1221); *Frequency:* Annually; *Affected Public:* Public sector (Individuals and Households), Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 90,015; *Total Annual Responses:* 90,015; *Total Annual Hours:* 22,523. (For policy questions regarding this collection contact Nidhi Singh Shah at 301–492–5110.)

Dated: July 20, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Behavioral Interventions to Advance Self-Sufficiency Next Generation (BIAS-NG).

OMB No.: New Collection.

Description: The Office of Planning, Research and Evaluation (OPRE) in the Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) requests Office of Management and Budget (OMB) approval for a 3-year pilot generic clearance to collect data as part of rapid cycle testing and evaluation, in order to inform the design of interventions informed by behavioral science and to better understand the mechanisms and effects of such interventions. These interventions, which will be in the program area domains of Temporary Assistance for Needy Families (TANF) and child welfare, are intended to improve outcomes for participants in these programs.

OPRE plans to conduct the Behavioral Interventions to Advance Self-Sufficiency Next Generation (BIAS-NG) project. This project will use behavioral insights to design and test interventions intended to improve the efficiency, operations, and efficacy of human services programs. The BIAS-NG project will apply behavioral insights to a range of ACF programs including TANF, Child Welfare, and other program areas to be determined. This notice is specific to data collection with TANF and Child Welfare sites; when and if the project desires to work in other program areas, OPRE will publish a **Federal Register** notice allowing for public comment and will submit a new information collection request for that work. Under this pilot generic clearance, OPRE plans to work with approximately six sites to conduct approximately two tests per site, for a total of approximately 12 tests of behavioral interventions.

The design and testing of BIAS NG interventions will be rapid and iterative. Each specific intervention will be

designed in consultation with agency leaders and launched quickly. To maximize the likelihood that the intervention produces measurable, significant, positive effects on outcomes of interest, rapid cycle evaluation techniques will be employed in which proximate outcomes will be measured to allow the research team to rapidly iterate and adjust the intervention design, informing subsequent tests.

Due to the rapid and iterative nature of this work OPRE seeks generic clearance to conduct this research. Following standard OMB requirements for generic clearances, once instruments are tailored to a specific site and the site's intervention, OPRE will submit an individual generic information collection request under this umbrella clearance. Each request will include the individual instrument(s), a justification specific to the individual information collection, a description of the proposed intervention, and any supplementary documents. Each specific information collection will include two submissions: First, a submission for the formative stage research and second, a submission for the test and evaluation materials. In this notice we describe the types of information expected to be collected for each test and the expected burden.

To ensure maximal relevance to the domain areas selected (*i.e.*, Child Welfare and TANF), the project has identified a set of broad problems that affect entire domain areas rather than problems that are idiosyncratic to a particular program. In each of the approximately six sites with which the project will work under this clearance, interventions will be designed and tested using an approach called behavioral diagnosis and design which will involve determining how identified problems operate within each site's specific context, diagnosing behavioral reasons for those problems, designing interventions informed by behavioral insights, and rigorously testing the interventions. Information will be collected throughout this process. The information that will be collected is specific to each of the sites, will not be collected indefinitely, and is not intended to be interpreted as applicable to other sites or to other programs. In addition, in working with the project to design the behavioral interventions to be tested, some sites may decide to change what data they collect and/or the questions they ask the public to answer. Such decisions will be controlled by the sites, not by the project.

In order to define and diagnose program challenges and design appropriate interventions, OPRE plans to conduct interviews and focus groups

with administrators, staff, and/or clients in each of the approximately six sites. OPRE will field client and/or staff surveys in order to hear from a breadth of perspectives. In addition to interviews, focus groups, and surveys, OPRE anticipates observing program activities and reviewing documents and administrative data. This information will be critical to diagnosing where and why programs are facing challenges and which behavioral interventions may have an impact.

During the testing phase OPRE anticipates conducting mixed-methods evaluations consisting of implementation, impact, and cost research for the approximately two tests in each of the approximately six total

sites that will be engaged across the two program areas included under this clearance, TANF and Child Welfare (for a total of 12 tests). To better understand how the intervention is being implemented and its effects, OPRE anticipates conducting interviews and focus groups with program administrators, staff, and/or clients in each site. Because not all outcomes of interest (for example, improved understanding of and/or satisfaction with the foster parent recruitment process) are reflected in administrative records, OPRE anticipates conducting client surveys and staff surveys.

Interest in participating in BIAS-NG is expected to be high, and it is not expected that systematic recruitment of

sites will be necessary. Within each site, we do not intend to do any active recruitment as all those who are eligible will be enrolled in the study and randomization will be conducted using a list of those who meet the eligibility criteria. Findings from these tests will be publicized through multiple dissemination channels, which may include but are not limited to reports on individual tests, a final synthesis report, presentations at conferences and meetings, scholarly journal articles, webinars, social media, press outreach, newsletters, etc.

Respondents: (1) Program Administrators, (2) Program Staff and (3) Program Clients.

TOTAL BURDEN HOURS

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Diagnosis and Design Phase				
Administrator interviews/focus groups	24	1	1	24
Staff interviews/focus groups	48	1	1	48
Client interviews/focus groups	48	1	1	48
Client survey	600	1	.25	150
Staff Survey	120	1	.25	30
Evaluation Phase				
Administrator interviews/focus groups	48	1	1	48
Staff interviews/focus groups	96	1	1	96
Client interviews/focus groups	96	1	1	96
Client Survey	6,000	1	.25	1,500
Staff survey	120	1	.25	30

Estimated Total Burden Hours: 2,070 hours.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: OPREinfocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn:

Desk Officer for the Administration for Children and Families.

Mary Jones,
ACF/OPRE, Certifying Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-4180]

Voluntary Medical Device Manufacturing and Product Quality Program; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public

workshop entitled “Voluntary Medical Device Manufacturing and Product Quality Program.” The purpose of the public workshop is to announce the proposed framework and preliminary outline of a voluntary pilot program that recognizes an independent assessment of manufacturing and product quality. The workshop is intended to discuss the framework of the voluntary pilot program, information on the independent assessment, details of participation, rules of engagement, monitoring and performance expectations, as well as potential modifications to FDA’s oversight actions in response to demonstrated manufacturing quality performance. FDA is soliciting public feedback to aid in the development of science-based approaches to regulatory decision making for assessing manufacturing quality, extent of manufacturing related submissions, and how to better allocate resources to lower the regulatory burden on manufacturers and FDA.