

are in “Category 2.” In the FPL the Council approved approximately \$156.6 million in Category 1 restoration and planning activities, and prioritized twelve Category 2 activities for possible funding in the future, subject to environmental compliance and further Council and public review. The Council included planning activities for Palm River in Category 1 and implementation activities for Palm River in Category 2.

The Council reserved approximately \$26.6 million for implementing priority activities in the future. These reserved funds may be used to support some, all or none of the activities included in Category 2 of the FPL and/or to support other activities not currently under consideration by the Council. As appropriate, the Council intends to review each activity in Category 2 in order to determine whether to: (1) Move the activity to Category 1 and approve it for funding, (2) remove it from Category 2 and any further consideration, or (3) continue to include it in Category 2. A Council decision to amend the FPL to move an activity from Category 2 into Category 1 must be approved by a Council vote after consideration of public and Tribal comments.

II. Environmental Compliance

Prior to approving an activity for funding in FPL Category 1, the Council must comply with NEPA and other applicable Federal environmental laws. At the time of approval of the FPL, the Council had not addressed NEPA and other laws applicable to implementation of Palm River. The Council did, however, recognize the potential ecological value of Palm River, based on a review conducted during the FPL process. For this reason, the Council approved \$87,750 in planning funds for Palm River, a portion of which would be used to complete any needed environmental compliance activities. As noted above, the Council placed the implementation portion of Palm River into FPL Category 2, pending the outcome of this environmental compliance work and further Council review. The estimated cost of implementation of the Florida portion of Palm River is \$497,250. As discussed earlier, EPA sponsored another component of Palm River, which was also placed in FPL Category 2. The estimated implementation cost of the EPA component is \$271,430. As noted above, the Council is proposing to unify both components under one sponsor (Florida).

Since approval of the FPL, Florida, EPA, and Council staff have collaborated with the U.S. Army Corps

of Engineers (USACE) to identify an existing EA and associated environmental compliance documentation that could be used to support Council approval of implementation funding for Palm River. This EA was prepared by USACE in association with a CWA Section 404 nationwide permit (NWP 27) for aquatic habitat restoration, establishment and enhancement activities.

The Council has reviewed this EA and associated documents, including a July 31, 2014, USACE memorandum for the record documenting use of NWP 27 for Palm River and a February 22, 2017, U.S. Fish and Wildlife Service letter to the Council regarding compliance with the Endangered Species Act (ESA). In addition to ESA, the EA and associated documents address compliance with other Federal environmental laws, including the Magnuson-Stevens Fishery Conservation and Management Act, the National Historic Preservation Act, and others. Based on this review, the Council is proposing to adopt this EA to support the approval of implementation funds for Palm River, provided that the project is implemented in accordance with the terms and conditions of the CWA Section 404 permit. This EA and the associated documentation can be found here: <https://www.restorethegulf.gov/funded-priorities-list>. (See: *Palm River Restoration Project Phase II, East McKay Bay—Implementation*.)

Palm River Project

If approved for implementation funding, the Palm River project would entail construction of three stormwater ponds, exotic vegetation removal, native planting, monitoring, and perpetual maintenance of exotic species and the culverts/stormwater ponds along the Palm River at the mouth of McKay Bay. Specifically, the Palm River project would improve water quality and enhance upland and wetland areas on 53 acres of Southwest Florida Water Management District land. It would remove exotic vegetation, create an herbaceous wetland, and build three stormwater management areas to provide water quality treatment for 436 acres of residential, commercial and industrial developed land.

Additional information on this Project, including metrics of success, response to science reviews and more is available in an activity-specific appendix to the FPL, which can be found at <https://www.restorethegulf.gov>. (Please see the table on page 25 of the FPL and click on: Palm River

Restoration Project Phase II, East McKay Bay, Implementation.)

Will D. Spoon,

Program Analyst, Gulf Coast Ecosystem Restoration Council.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) reapprove the information collection project: “*Consumer Assessment of Healthcare Providers and Systems (CAHPS) Health Plan Survey Comparative Database*.” In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on December 22, 2016 and allowed 60 days for public comment. Since AHRQ did not receive any substantive comments during this period, this notice allows for an additional 30 days for public comment.

DATES: Comments on this notice must be received by April 17, 2017.

ADDRESSES: Written comments should be submitted to: AHRQ’s OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ’s desk officer) or by email at OIRA_submission@omb.eop.gov (attention: AHRQ’s desk officer).

FOR FURTHER INFORMATION CONTACT:

Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Consumer Assessment of Healthcare Providers and Systems (CAHPS) Health Plan Survey Comparative Database

The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) reapprove, under the Paperwork

Reduction Act of 1995, AHRQ's collection of information for the AHRQ Consumer Assessment of Healthcare Providers and Systems (CAHPS) Database for Health Plans: OMB Control number 0935-0165, expiration May 31, 2017. The CAHPS Health Plan Database consists of data from the AHRQ CAHPS Health Plan Survey. Health plans in the U.S. are asked to submit data voluntarily from the survey to AHRQ through its contractor, Westat. The CAHPS Database was developed by AHRQ in 1998 in response to requests from health plans, purchasers, the Centers for Medicare and Medicaid Services (CMS) to provide comparative data to support public reporting of health plan ratings, health plan accreditation and quality improvement.

This research has the following goals:

(1) To maintain the CAHPS Health Plan database using data from AHRQ's standardized CAHPS Health Plan survey to provide comparative results to health care purchasers, consumers, regulators and policy makers across the country.

(2) To offer several products and services, including comparative benchmark results presented through an Online Reporting System, summary chartbooks, custom analyses, and data for research purposes.

(3) To provide data for AHRQ's annual National Healthcare Quality and Disparities Report.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

To achieve the goals of this project the following data collections will be implemented:

(1) CAHPS Health Plan Survey that includes the Adult Medicaid, Child

Medicaid and State Children's Health Insurance Program (SCHIP) populations. The Adult data collection uses the Adult survey and the Child and SCHIP collections include a child survey with chronic conditions and a child survey without chronic condition items. The CAHPS Health Plan surveys ask enrollees about their recent experiences with health plans and their services. This standardized survey was designed to support consumers in assessing the performance of health plans and choosing the plans that best meet their needs. Health plans can also use the survey results to identify their strengths and weaknesses and target areas for improvement. Participants have access to resources regarding the data submission process, a user guide and a technical assistance help line.

(2) Medicare health plan data are received from CMS.

Survey data from the CAHPS Health Plan Database is used to produce four types of products: (1) An annual chartbook available to the public on the CAHPS Database Web site (<https://www.cahpsdatabase.ahrq.gov/CAHPSIDB/Public/Chartbook.aspx>); (2) individual participant comparative reports that are confidential and customized for each participating organization (e.g., health plan, Medicaid agency) that submits their data; (3) a research database available to researchers wanting to conduct additional analyses; and (4) data tables provided to AHRQ for inclusion in the National Healthcare Quality and Disparities Report.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated burden hours for the respondent to participate in the database. The burden hours pertain only to the collection of Medicaid data from State Medicaid agencies and individual Medicaid health plans because those are the only entities that submit data through the data submission process (other data are obtained from CMS as noted earlier in Section 2). The 85 Point of Contact

(POC)s in Exhibit 1 are a combination of an estimated 75 State Medicaid agencies and individual health plans, and 10 vendor organizations.

Each State Medicaid agency, health plan or vendor will register online for submission. The online Registration form will require about 5 minutes to complete. Each submitter will also complete a Health Plan information form of information about each Health Plan such as the name of the plan, the product type (e.g., HMO, PPO), the population surveyed (e.g., adult Medicaid or child Medicaid). Each year, the prior year's plan data are preloaded in the plan table to lessen burden on the Sponsor. The Sponsor is responsible for updating the plan table to reflect the current year's plan information. The online Health Plan Information form takes on average 30 minutes to complete per health plan with each POC completing the form for 4 plans on average. The data use agreement will be completed by the 75 participating State Medicaid agencies or individual health plans. Vendors do not sign or submit DUAs. The DUA requires about 3 minutes to sign and return by fax or mail. Each submitter will provide a copy of their questionnaire and the survey data file in the required file format. Survey data files must conform to the data file layout specifications provide by the CAHPS Database. Since the unit of analysis is at the health plan level, submitters will upload one data file per health plan. Once a data file is uploaded the file will be checked automatically to ensure it conforms to the specifications and a data file status report will be produced and made available to the submitter. Submitters will review each report and will be expected to fix any errors in their data file and resubmit if necessary. It will take about 1 hour to submit the data for each plan, and each POC will submit data for 4 plans on average. The total burden is estimated to be 501 hours annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Registration Form	85	1	5/60	7
Health Plan Information Form	75	4	30/60	150
Data Use Agreement	75	1	3/60	4
Data Files Submission	85	4	1	340
Total	320	NA	NA	501

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to complete one

submission process. The cost burden is estimated to be \$22,153 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Registration Form	85	7	^a 50.99	\$357
Health Plan Information Form	75	150	^a 50.99	7,649
Data Use Agreement	75	4	^b 89.35	357
Data Files Submission	85	340	^c 40.56	13,790
Total	320	501	NA	22,153

* National Compensation Survey: Occupational wages in the United States May 2015, "U.S. Department of Labor, Bureau of Labor Statistics."

^a Based on the mean hourly wage for Medical and Health Services Managers (11–9111).

^b Based on the mean hourly wage for Chief Executives (11–1011).

^c Based on the mean hourly wages for Computer Programmer (15–1131).

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,
Acting Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0536]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Pharmacogenomic Data Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection resulting from the submission to the Agency of pharmacogenomic data during the drug development process.

DATES: Submit either electronic or written comments on the collection of information by May 16, 2017.

ADDRESSES: You may submit comments 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://](https://www.regulations.gov)

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):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2010-N-0536 for "Guidance for Industry on Pharmacogenomic Data Submissions." 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