Dated: July 2, 2010.

Carol Walker,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection 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 on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Bureau of Primary Health Care (BPHC) Uniform Data System (OMB Clearance No. 0915–0193—Revision)

The Uniform Data System (UDS) contains the annual reporting requirements for the cluster of primary care grantees funded by the Health Resources and Services Administration (HRSA). The UDS includes reporting requirements for grantees of the following primary care programs: Community Health Centers, Migrant Health Centers, Health Care for the Homeless, Public Housing Primary Care, and other grantees under Section 330. The authorizing statute is section 330 of the Public Health Service Act, as amended.

HRSA collects data in the UDS which are used to ensure compliance with legislative mandates and to report to Congress and policymakers on program accomplishments. To meet these objectives, BPHC requires a core set of data collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends. The UDS will be revised in several ways. Certain data elements are added for staffing and utilization and for diagnoses, services, and tests. Specifications for current clinical measures are revised to align with those of national standard setting organizations. Revenue sources are updated to include new federal revenue sources. A limited number of clinical measures will be added consistent with identified national priorities.

These new measures are included in the UDS data collection request in order to allow advance time for health centers to change data collection systems. These changes reflect an increase in burden of 18,224 hours over the previous information collection request in 2009. The burden is increased due to a greater number of respondents and reporting of the new measures.

Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Universal report	1,181	1	68	80,308
Grant report	328	1	18	5,904
Total	1,181			86,212

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: July 2, 2010.

Sahira Rafiullah,

Director, Division of Policy Information and Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0316]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Pilot Program for Medical Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 continuation of a pilot project to evaluate the electronic collection of the 3500A Form for adverse events related to the use of medical products to obtain data from user facilities participating in the Medical Product Safety Network (MedSun). Additionally, the electronic form will include hospital profile information and several other questions related to the use of medical products. It will no longer contain the page called Device-Safety Exchange (DS–X) (formerly called M-Den), which was a moderated site where MedSun members shared information with each other. This will be replaced by a page where questions about possible emerging