

“Submission of Patent Information for Certain Old Antibiotics.” That draft guidance, if finalized, would provide information regarding FDA’s current thinking on the implementation of section 4(b)(1) of the Q1 Program Supplemental Funding Act (Public Law 110–379). Section 4(b)(1) of the Q1 Act requires submission to FDA of patent information by sponsors of certain NDAs containing old antibiotics. Estimates on the number of Forms FDA 3542a and 3542 that might be submitted in accordance with a finalized guidance have been included in table 1 of this document.

Dated: July 1, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160–01–S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on

proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

*Comments are invited on:* (a) Whether the proposed collections of information are 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: Voluntary Customer Satisfaction Surveys To Implement Executive Order 12862 in the Substance Abuse and Mental Health Services Administration (SAMHSA)—(OMB No. 0930–0197)—Extension**

Executive Order 12862 directs agencies that “provide significant services directly to the public” to

“survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services.” SAMHSA provides significant services directly to the public, including treatment providers and State substance abuse and mental health agencies, through a range of mechanisms, including publications, training, meetings, technical assistance and web sites. Many of these services are focused on information dissemination activities. The purpose of this submission is to extend the existing generic approval for such surveys.

The primary use for information gathered is to identify strengths and weaknesses in current service provisions by SAMHSA and to make improvements that are practical and feasible. Several of the customer satisfaction surveys expected to be implemented under this approval will provide data for measurement of program effectiveness under the Government Performance and Results Act (GPRA). Information from these customer surveys will be used to plan and redirect resources and efforts to improve or maintain a high quality of service to health care providers and members of the public. Focus groups may be used to develop the survey questionnaire in some instances.

The estimated annual hour burden is as follows:

Type of data collection	Number of respondents	Responses/ respondent	Hours/ response	Total hours
Focus groups .....	250	1	2.50	625
Self-administered, mail, telephone and e-mail surveys .....	89,750	1	.250	22,438
<b>Total .....</b>	<b>90,000</b>	<b>.....</b>	<b>.....</b>	<b>23,063</b>

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 and e-mail her a copy at [summer.king@samhsa.hhs.gov](mailto:summer.king@samhsa.hhs.gov). Written comments should be received within 60 days of this notice.

Dated: June 30, 2010.

**Dennis O. Romero,**

*Deputy Director, Office of Program Services.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60-Day 10–0214]**

**Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c) (2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed project or to obtain a copy of data collection plans and instruments, call the CDC Reports Clearance Officer

on 404–639–5960 or send comments to CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS D–74, Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

*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 the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

**Proposed Project**

National Health Interview Survey (NHIS), (OMB No. 0920-0214)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability of the population of the United States.

The annual National Health Interview Survey (NHIS) is a major source of general statistics on the health of the U.S. population and has been in the field continuously since 1957. On January 4, 2010, the Office of Management and Budget (OMB) approved data collection for the 2010, 2011, and 2012 surveys. This revision is to notify the public that the President's fiscal year 2011 budget requests that Congress consider a budget increase for this survey for 2011. If the budget increase is approved by Congress, expanded data collection will begin in the first calendar quarter of 2011 or as

soon thereafter as is possible. A maximum sample increase of approximately 23 percent (from 35,000 participating households to approximately 43,000 households) is requested. Currently the NHIS produces National and regional estimates with some estimates available for a limited number of States. If the full budget increase is approved by Congress, the survey will be able to produce a larger number of estimates for approximately 30 additional States and key population subgroups.

Congress may approve all, some or none of the budget increase requested in the President's budget. If approved, this notice would allow the proposed request for a sample increase to move forward to OMB for final review in sufficient time to implement the sample increase in the first quarter of 2011. This notice also covers increases in sample size that might result due to other budget allocations.

This voluntary household-based survey collects demographic and health-related information on a nationally representative sample of persons and households throughout the country. Information is collected using computer assisted personal interviews (CAPI). A

core set of data is collected each year while sponsored supplements vary from year to year. Personal identification information is requested from survey respondents to facilitate linkage of survey data with health related administrative and other records.

In accordance with the 1995 initiative to increase the integration of surveys within the Department of Health and Human Services, respondents to the NHIS serve as the sampling frame for the Medical Expenditure Panel Survey conducted by the Agency for Healthcare Research and Quality. The NHIS has long been used by government, university, and private researchers to evaluate both general health and specific issues, such as cancer, diabetes, and access to health care. It is a leading source of data for the Congressionally-mandated "Health US" and related publications, as well as the single most important source of statistics to track progress toward the National Health Promotion and Disease Prevention Objectives, "Healthy People 2010." This submission requests approval for three years.

There is no cost to the respondents other than their time.

ANNUALIZED BURDEN TABLE

Questionnaire (respondent)	Number of respondents	Number of responses per respondent	Average burden per respondent in hours	Total burden in hours
Screener Questionnaire .....	13,000	1	5/60	1,083
Family Core (adult family member) .....	43,000	1	23/60	16,483
Adult Core (sample adult) .....	32,500	1	14/60	7,583
Child Core (adult family member) .....	13,000	1	9/60	1,950
Child and Adult Immunization (adult family member) .....	12,500	1	3/60	625
Family Disability (adult family member) .....	21,500	1	3/60	1,075
Veteran Status/Service Dates (adult family member) .....	43,000	1	1/60	717
Adult Voice, Speech, Swallowing, and Language (sample adult) .....	32,500	1	4/60	2,167
Child Voice, Speech, Swallowing, and Language (adult family member) .....	13,000	1	1/60	217
Family Food Security (adult family member) .....	43,000	1	2/60	1,433
Health Care Reform (adult family member) .....	43,000	1	5/60	3,583
Functioning and Disability (sample adult) .....	16,250	1	3/60	813
Fitness Center Use (sample adult) .....	32,500	1	1/60	542
Child Record Check (medical provider) .....	1,500	1	5/60	125
Teen Record Check (medical provider) .....	6,250	1	5/60	521
Child Mental Health (adult family member) .....	13,000	1	1/60	217
Mental Health Services (adult Family member) .....	13,000	1	3/60	650
Reinterview Survey .....	3,900	1	5/60	325
<b>Total Burden Hours .....</b>				<b>40,109</b>

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
<b>Total .....</b>	<b>1,181</b>	<b>.....</b>	<b>.....</b>	<b>86,212</b>

E-mail comments to [paperwork@hrsa.gov](mailto: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