The NHAMCS provides a range of baseline data on the characteristics of the users and providers of ambulatory medical care. Data collected include patients' demographic characteristics and reason(s) for visit, and the physicians' diagnosis(es), diagnostic equipment and services, medications, and disposition. These data, together with trend data, may be used to monitor the effects of change in the health care system, for the planning of health services, improving medical education, determining health care work force needs, and assessing the health status of the population.

Users of NHAMCS data include, but are not limited to, congressional offices, Federal agencies such as NIH, state and local governments, schools of public health, colleges and universities, private industry, nonprofit foundations, professional associations, as well as individual practitioners, researchers, administrators, and health planners. Uses vary from the inclusion of a few selected statistics in a large research effort, to an in-depth analysis of the entire NHAMCS data set covering several years.

To calculate the burden hours the number of respondents for the NHAMCS is based on an annual sample of approximately 500 hospitals with an 94 percent participation rate. The total cost to respondents is estimated to be $300,000.

Respondents (non-Federal general and short-stay hospitals)	Number of respondents	Number of responses/respondent	Avg. burden/response (in hrs.)	Response burden (in hrs.)
Induction forms:				
Ineligible hospitals	50	1	15/60	13
Eligible hospitals	440	1	1	440
Emergency departments	400	1	1	400
Outpatient departments	240	4	1	960
Patient record forms:				
Emergency departments	400	100	5/60	3,333
Outpatient departments	240	200	5/60	4,000
Pediatric emergency services and equipment	400	1	30/60	200
Total				9,346

Dated: November 30, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–02–13]

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 projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

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. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: National Ambulatory Medical Care Survey OMB No. 0920–0234—Revision—National Center for Health Statics (NCHS), Centers for Disease Control and Prevention, (CDC). The National Ambulatory Medical Care Survey (NAMCS) was conducted annually from 1973 to 1981, again in 1985, and resumed as an annual survey in 1989. It is directed by the Division of Health Care Statistics, National Center for Health Statistics, CDC. The purpose of NAMCS is to meet the needs and demands for statistical information about the provision of ambulatory medical care services in the United States. Ambulatory services are rendered in a wide variety of settings, including physicians' offices and hospital outpatient and emergency departments. The NAMCS target population consists of all office visits within the United States made by ambulatory patients to non-Federal office-based physicians (excluding those in the specialties of anesthesiology, radiology, and pathology) who are engaged in direct patient care. Since more than 80 percent of all direct ambulatory medical care visits occur in physicians' offices, the NAMCS provides data on the majority of ambulatory medical care services. To complement these data, in 1992 NCHS initiated the National Hospital Ambulatory Medical Care Survey (NHAMCS, OMB No. 0920–0278) to provide data concerning patient visits to hospital outpatient and emergency departments. The NAMCS, together with the NHAMCS constitute the ambulatory component of the National Health Care Survey (NHCS), and will provide coverage of more than 90 percent of ambulatory medical care.

The NAMCS provides a range of baseline data on the characteristics of the users and providers of ambulatory medical care. Data collected include the patients' demographic characteristics and reason(s) for visit, and the physicians' diagnosis(es) and diagnostic services, medications and disposition. These data, together with trend data, may be used to monitor the effects of change in the health care system, provide new insights into ambulatory medical care, and stimulate further research on the use, organization, and delivery of ambulatory care.

Users of NAMCS data include, but are not limited to, congressional and other

federal government agencies such as NIH and FDA, state and local governments, medical schools, schools of public health, colleges and universities, private businesses, nonprofit foundations and corporations, professional associations, as well as individual practitioners, researchers, administrators and health planners. Uses vary from the inclusion of a few selected statistics in a large research effort, to an in-depth analysis of the entire NAMCS data set covering several years.

To calculate the burden hours the number of respondents for NAMCS is based on a sample of 3,150 physicians with a 50 percent participation rate (this includes physicians who are out-of-scope as well as those who refuse). The total cost to respondents is estimated to be $300,000.

Respondents	Number of respondents	Number of response/respondent	Avg. burden/responses (in hrs.)	Response burden (in hrs.)
Office-based physicians Induction form	1,575	1	25/60	656
Patient record form	1,575	30	5/60	3,938
Total				4,594

Dated: November 30, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0496]

Patient Profile Viewer; Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is seeking volunteers to participate in a pilot project involving the testing of the Patient Profile Viewer (PPV). The PPV is computer software that allows a reviewer to display data collected from case report tabulations (CRTs) submitted in electronic format. We are working with PPD Informatics to develop the PPV under a Cooperative Research and Development Agreement (CRADA) in an effort to improve review efficiency, develop standards for submission of data, and eliminate the need for the submission of patient profiles by applicants of new drug applications (NDAs). To help in this development, we are seeking volunteers to provide CRT datasets from clinical studies to test the PPV. Data supplied during the pilot project will not replace any regulatory requirements for submitting CRTs.

DATES: Submit written or electronic requests to participate in the pilot project by January 9, 2002. Comments on the pilot project may be submitted at any time.

ADDRESSES: Submit written requests to participate and comments regarding this pilot project to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the pilot project to the Dockets Management Branch (address above). Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Randy Levin, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5411, e-mail: levinr@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under current FDA regulations (21 CFR 314.50), applicants must provide CRTs with NDAs. Since November 1997, under 21 CFR part 11, we have accepted CRTs in electronic format instead of paper.

We have published several guidance documents that provide recommendations concerning electronic submissions. In the **Federal Register** of January 28, 1999 (64 FR 4432), CDER published the guidance entitled ''Providing Regulatory Submissions in Electronic Format—NDAs.'' This guidance describes how applicants can provide CRTs as electronic datasets. This guidance also offers recommendations on how to organize the datasets and how to provide descriptive information on the datasets and the data variables (metadata). In the **Federal Register** of November 12, 1999 (64 FR 61647), the Center for Biologics Evaluation and Research (CBER) provides similar recommendations for biologic license applications (BLAs) in their guidance entitled ''Providing Regulatory Submissions in Electronic Format—BLAs.'' A joint CBER and CDER guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—General Considerations,'' provides recommendations for the file formats for clinical datasets (64 FR 4433, January 28, 1999).

The datasets described in these guidance documents are organized by domain (e.g., labs, adverse events). For NDAs, however, we also recommend the submission of CRTs organized by individual patients—a format we call patient profiles. Patient profiles are provided in portable document format (PDF) and not as electronic datasets. Patient profiles are not recommended for submissions to CBER. CDER is working with CBER to update the guidance documents with more detailed standards for the submission of CRT datasets and metadata.

Recently, we have received recommendations for a standard presentation of the most common CRT datasets and metadata from the Clinical Data Interchange Standards Consortium, Inc. (CDISC). CDISC is a nonprofit organization and its members are from pharmaceutical companies, biotechnology companies, contract research organizations, and software vendors.

CDER has also entered into a CRADA with PPD Informatics (PPD) to develop a module for PPD's commercially available CrossGraphs software that will generate patient profiles directly from CRT datasets provided with NDA submissions. The use of standardized datasets and metadata reduces the amount of preparation required by the reviewer to generate patient profiles and would eliminate the need for applicants to provide patient profiles in PDF. The purpose of the pilot project is to test the PPV module with standardized datasets and metadata and to obtain feedback from reviewers and pharmaceutical