

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Determination Concerning a Petition To Add a Class of Employees to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a determination concerning a petition to add a class of employees from Titanium Alloys Manufacturing in Niagara Falls, New York, to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. 7384q. On August 23, 2012, the Secretary of HHS determined that the following class of employees does not meet the statutory criteria for addition to the SEC as authorized under EEOICPA:

All employees who worked in any area or building at Titanium Alloys Manufacturing from January 1, 1955, through December 31, 1956.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 1-877-222-7570. Information requests can also be submitted by email to DCAS@CDC.GOV.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2012-23276 Filed 9-19-12; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold its twenty-ninth meeting. The meeting will be open to the public. Information about

SACHRP and the full meeting agenda will be posted on the SACHRP Web site at: <http://www.hhs.gov/ohrp/sachrp/mtginfo/index.html>.

DATES: The meeting will be held on Tuesday, October 9, 2012 from 8:30 a.m. until 5:00 p.m. and Wednesday, October 10, 2012 from 8:30 a.m. until 4:30 p.m.

ADDRESSES: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 705A, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP), or Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; 240-453-8141; fax: 240-453-6909; email address: Julia.Gorey@hhs.gov.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human research subjects.

The meeting will open Tuesday, October 9, with remarks from SACHRP Chair Dr. Barbara Bierer and OHRP Director Dr. Jerry Menikoff, followed by a report from the Subpart A Subcommittee (SAS). SAS will discuss their recent work, including considerations for revisions to the expedited review list, principal investigator responsibilities, and informed consent waiver criteria. SAS is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment; this subcommittee was established by SACHRP in October 2006. Tuesday afternoon will be a discussion of informed consent issues in cluster randomized trials, featuring Dr. Andrew McRae, Research Director of the Division of Emergency Medicine, University of Calgary.

On the morning of October 10, the Subcommittee on Harmonization (SOH) will give a report and discuss their recent work, including local context guidance recommendations. SOH was established by SACHRP at its July 2009 meeting, and is charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would

benefit from harmonization, consistency, clarity, simplification and/or coordination. Wednesday afternoon SACHRP will discuss a revised document on the issue of the use of the Internet in human subjects research, drafted by Drs. Elizabeth Buchanan and Dean Gallant. Public Comment will be heard on both days.

Public attendance at the meeting is limited to space available. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact persons. Members of the public will have the opportunity to provide comments on both days of the meeting. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed materials distributed to SACHRP members for this scheduled meeting should submit materials to the Executive Director, SACHRP, prior to the close of business October 1, 2012.

Dated: September 13, 2012.

Jerry Menikoff,

Director, Office for Human Research Protections, Executive Secretary, Secretary's Advisory Committee on Human Research Protections.

[FR Doc. 2012-23143 Filed 9-19-12; 8:45 am]

BILLING CODE 4150-36-P

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) approve the proposed information collection project: "Online Application Order Form for Products from the Healthcare Cost and Utilization Project (HCUP)." 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 June 27th, 2012 and allowed 60 days for public comment. Several comments were received. The purpose

of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by October 22, 2012.

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).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance 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

Online Application Order Form for Products From the Healthcare Cost and Utilization Project (HCUP)

The Healthcare Cost and Utilization Project (HCUP, pronounced "H-Cup") is a vital resource helping AHRQ achieve its research agenda, thereby furthering its goal of improving the delivery of health care in the United States. HCUP is a family of health care databases and related software tools and products developed through a Federal-State-Industry partnership and sponsored by AHRQ. HCUP includes the largest collection of longitudinal hospital care data in the United States, with all-payer, encounter-level information beginning in 1988. The HCUP databases are annual files that contain anonymous information from hospital discharge records for inpatient care and certain components of outpatient care, such as emergency care and ambulatory surgeries. The project currently releases a variety of databases created for research use on a broad range of health issues, including cost and quality of health services, medical practice patterns, access to health care programs, and outcomes of treatments at the national, State, and local market levels. HCUP also produces a large number of software tools to enhance the use of administrative health care data for research and public health use. Software tools use information available from a variety of sources to create new data elements, often through sophisticated algorithms, for use with the HCUP databases.

HCUP's objectives are to:

- Create and enhance a powerful source of national, state, and all-payer health care data.

- Produce a broad set of software tools and products to facilitate the use of HCUP and other administrative data.

- Enrich a collaborative partnership with statewide data organizations (that voluntarily participate in the project) aimed at increasing the quality and use of health care data.

- Conduct and translate research to inform decision making and improve health care delivery.

The HCUP releases six types of databases for public research use:

(1) The Nationwide Inpatient Sample (NIS) is the largest all-payer inpatient care database in the United States, containing data from approximately 8 million hospital stays from roughly 1,000 hospitals; this approximates a 20-percent stratified sample of U.S. community hospitals. NIS data releases are available for purchase from the HCUP Central Distributor for data years beginning in 1988.

(2) The Kids' Inpatient Database (KID) is the only all-payer inpatient care database for children in the United States. The KID was specifically designed to permit researchers to study a broad range of conditions and procedures related to child health issues. The KID contains a sample of over 3 million discharges for children age 20 and younger from more than 3,500 U.S. community hospitals.

(3) The Nationwide Emergency Department Sample (NEDS) is the largest all-payer ED database in the United States. It is constructed to capture information both on ED visits that do not result in an admission and on ED visits that result in an admission to the same hospital. The NEDS contains more than 25 million unweighted records for ED visits at about 1,000 U.S. community hospitals and approximates a 20-percent stratified sample of U.S. hospital-based EDs. Files are available beginning with data year 2006.

(4) The State Inpatient Databases (SID) contain the universe of inpatient discharge abstracts from data organizations in 46 States that currently participate in the SID. Together, the SID encompasses approximately 97 percent of all U.S. community hospital discharges. Most States that participate in the SID make their data available for purchase through the HCUP Central Distributor. Files are available beginning with data year 1990.

(5) The State Ambulatory Surgery Databases (SASD) contain data from ambulatory care encounters in hospital-affiliated (and sometimes freestanding) ambulatory surgery sites. Currently, 29 States participate in the SASD. Files are available beginning with data year 1997.

(6) The State Emergency Department Databases (SEDD) contain data from hospital-affiliated emergency department (ED) abstracts for visits that do not result in a hospitalization. Currently, 29 States participate in the SEDD. Files are available beginning with data year 1999.

To support AHRQ's mission to improve health care through scientific research, HCUP databases and software tools are disseminated to users outside of the Agency through a mechanism known as the HCUP Central Distributor. The HCUP Central Distributor assists qualified researchers to access uniform research data across multiple states with the use of one application process. The HCUP databases disseminated through the Central distributor are referred to as "restricted access public release files;" that is, they are publicly available, but only under restricted conditions.

HCUP databases are released to researchers outside of AHRQ after the completion of required training and submission of an application that includes a signed FICUP Data Use Agreement (DUA). In addition, before restricted access public release state-level databases are released, the user is asked for a brief description of their research to ensure that the planned use is consistent with HCUP policies and with the FICUP data use requirements. Fees are set for databases released through the HCUP Central Distributor depending on the type of database. The fee for sale of state-level data is determined by each participating Statewide Data Organization and reimbursed to those organizations. This project is being conducted by AHRQ through its contractor and subcontractor, Thomson Reuters and Social & Scientific Systems, Inc., pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the outcomes, cost, cost-effectiveness, and use of health care services and access to such services. (42 U.S.C. 299a(a)(3).)

Method of Collection

This information collection request is for the activities associated with completing an online application form to request HCUP data, not the collection of health care data for HCUP databases. The activities associated with the HCUP online application include:

(1) HCUP Application Form. All persons wanting access to the HCUP databases must complete an application package. Each unique database has a unique application package. All application packages are available for

downloading at http://www.hcup-us.ahrq.gov/tech_assist/centdist.jsp.

(2) HCUP Data Use Agreement Training. All persons wanting access to the HCUP databases must complete this online training course. The purpose of the training is to emphasize the importance of data protection, reduce the risk of inadvertent violations, and describe the individual's responsibility when using HCUP data. The training course can be accessed and completed online at http://www.hcup-us.ahrq.gov/tech_assist/dua.jsp.

(3) HCUP Data Use Agreement (DUA). All persons wanting access to the HCUP databases must sign a data use agreement. Each database has a unique DUA; an example DUA for the Nationwide Inpatient Sample database is available at <http://www.hcup-us.ahrq.gov/team/NISDUA.jsp>.

Information collected in the HCUP Application Order Form will be used for two purposes only:

1. *Business Transaction*: HCUP databases and software are currently delivered on disk and shipped to users who have completed the application process. Contact information is used for shipping the data on disk (or any other media used in the future). AHRQ policy and current agreements with Statewide Data Organizations contributing data to HCUP prohibit providing access to the data via the Internet or email.

2. *Enforcement of the HCUP Data Use Agreement (DUA)*: The HCUP DUA contains several restrictions on use of the data. Most of these restrictions have been put in place to safeguard the privacy of individuals and establishments represented in the data. For example, data users can only use the data for research, analysis, and aggregate

statistical reporting and are prohibited from attempting to identify any persons in the data. Contact information on HCUP Data Use Agreements is retained in the event that a violation of the DUA takes place.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden associated with the applicants' time to order any of the HCUP databases. An estimated 1,200 persons will order HCUP data annually. Each of these persons will complete an application (10 minutes), the DUA training (15 minutes) and a DUA (5 minutes). The total burden is estimated to be 600 hours annually.

Exhibit 2 shows the estimated annualized cost burden associated with the applicants' time to order HCUP data. The total cost burden is estimated to be \$21,408 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
HCUP Application Form	1,200	1	10/60	200
HCUP DUA Training	1,200	1	15/60	300
HCUP DUA	1,200	1	5/60	100
Total	3,600	na	na	600

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
HCUP Application Form	1,200	200	\$35.68	\$7,136
HCUP DUA Training	1,200	300	35.68	10,704
HCUP DUA	1,200	100	35.68	3,568
Total	3,600	600	na	21,408

*Based upon the mean of the average wages for Life Scientists, All Other (19–1099), National Compensation Survey: Occupational wages in the United States May 2011, "U.S. Department of Labor, Bureau of Labor Statistics."

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annualized cost to process HCUP

database applications and maintain the ordering system over the 3 years covered by this information collection request. It is estimated to cost \$17,237

annually to operate and maintain the ordering system.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Order Review	\$14,493	\$4,831
Monthly Updates—Product Catalog	1,857	619
System Maintenance	13,820	4,607
Customer Inquiries	4,483	1,495
Management/Troubleshooting	17,058	5,689
Total	51,711	17,237

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 healthcare research and healthcare 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.

Dated: September 13, 2012.

Carolyn M. Clancy,
Director.

[FR Doc. 2012-23165 Filed 9-19-12; 8:45 am]

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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) approve the proposed information collection project: "Medical Expenditure Panel Survey (MEPS) Household Component and the MEPS Medical Provider Component." 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 June 13th, 2012 and allowed 60 days for public comment. One comment was received. The purpose of

this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by October 22, 2012.

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).

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SUPPLEMENTARY INFORMATION:

Proposed Project

Medical Expenditure Panel Survey (MEPS) Household Component and the MEPS Medical Provider Component

For over thirty years, results from the MEPS and its predecessor surveys (the 1977 National Medical Care Expenditure Survey, the 1980 National Medical Care Utilization and Expenditure Survey and the 1987 National Medical Expenditure Survey) have been used by OMB, DHHS, Congress and a wide number of health services researchers to analyze health care use, expenses, and health policy.

Major changes continue to take place in the health care delivery system. The MEPS is needed to provide information about the current state of the health care system as well as to track changes over time. The MEPS permits annual estimates of use of health care and expenditures and sources of payment for that health care. It also permits tracking individual change in employment, income, health insurance and health status over two years. The use of the National Health Interview Survey (NHIS) as a sampling frame expands the MEPS analytic capacity by providing another data point for comparisons over time.

Households selected for participation in the MEPS Household Component (MEPS-HC) are interviewed five times in person. These rounds of interviewing are spaced about 5 months apart. The interview will take place with a family respondent who will report for him/herself and for other family members.

The MEPS-HC has the following goal:

- To provide nationally representative estimates for the U.S. civilian noninstitutionalized population for health care use, expenditures,

sources of payment and health insurance coverage.

The MEPS Medical Provider Component (MEPS-MPC) will contact medical providers (hospitals, physicians, home health agencies and institutions) identified by household respondents in the MEPS-HC as sources of medical care for the time period covered by the interview, and all pharmacies providing prescription drugs to household members during the covered time period. The MEPS-MPC is not designed to yield national estimates. The sample is designed to target the types of individuals and providers for whom household reported expenditure data was expected to be insufficient. For example, households with one or more Medicaid enrollees are targeted for inclusion in the MEPSMPC because this group is expected to have limited information about payments for their medical care.

The MEPS-MPC has the following goal:

- To serve as an imputation source for and to supplement/replace household reported expenditure and source of payment information. This data will supplement, replace and verify information provided by household respondents about the charges, payments, and sources of payment associated with specific health care encounters.

This study is being conducted by AHRQ through its contractors, Westat and RTI International, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the cost and use of health care services and with respect to health statistics and surveys. 42 U.S.C. 299a(a)(3) and (8); 42 U.S.C. 299b-2.

Method of Collection

To achieve the goals of the MEPS-HC the following data collections are implemented:

1. Household Component Core Instrument. The core instrument collects data about persons in sample households. Topical areas asked in each round of interviewing include condition enumeration, health status, health care utilization including prescribed medicines, expense and payment, employment, and health insurance. Other topical areas that are asked only once a year include access to care, income, assets, satisfaction with health plans and providers, children's health, and adult preventive care. While many of the questions are asked about the entire reporting unit (RU), which is