

SUPPORTING STATEMENT

Part A

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

Version April 24, 2012

Agency of Healthcare Research and Quality (AHRQ)

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A. Justification

1. Circumstances that make the collection of information necessary

The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see <http://www.ahrq.gov/hrqa99.pdf>), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. research that develops and presents scientific evidence regarding all aspects of health care; and
2. the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and
3. initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

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 six types 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.

This information collection request is for the activities associated with the HCUP database application process not the collection of health care data for HCUP databases. The activities associated with the HCUP database 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>.

HCUP databases are released to researchers outside of AHRQ after the completion of required training and submission of an application that includes a signed HCUP 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 HCUP 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).)

2. Purpose and Use of Information

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 e-mail.
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.

3. Use of Improved Information Technology

The HCUP application and DUA are available online but must be printed, completed by hand and mailed to HCUP staff. An online application order form is currently being developed that will use a software based data entry process to collect the required information and eliminate the need to print and mail the application form. Since the DUA must be signed this form cannot be completed entirely online. The DUA training can be completed entirely online.

Automating the HCUP database ordering process will streamline and facilitate the ordering process for HCUP database customers and result in a more efficient process for the Agency.

4. Efforts to Identify Duplication

No other source of data is available to allow AHRQ to deliver data to purchasers or allow follow up in the event of a DUA violation. This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Involvement of Small Entities

The information being requested has been held to the absolute minimum required for the intended use.

6. Consequences if Information Collected Less Frequently

Collection of information will take place one time for each application for data. To reduce burden, multiple products may be ordered using one application order form.

Without collection of information using the application ordering form, it will not be possible to implement an electronic ordering process and the opportunity to improve Agency efficiency and reduce public burden will not be possible.

7. Special Circumstances

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

8. Federal Register Notice and Outside Consultations

8.a. Federal Register Notice

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on June 27th, 2012 for 60 days, and again on September 20th, 2012 for 30 days (see Attachment A). No comments were received.

8.b. Outside Consultations

AHRQ did not consult with any outside individual or agency with respect to this new information collection. The information collection required for the electronic application order process is an absolute minimum for conducting the transaction and is modeled on a process already established by the National Technical Information Service (NTIS) at <http://www.ntis.gov/about/index.aspx>. AHRQ is unable to utilize NTIS for dissemination of HCUP databases and software because of special circumstances required for release of the data; 1) the need to review applications for state-level data to ensure that the planned use is consistent with HCUP policies and with the HCUP data use requirements, and 2) the need to retain copies of signed Data Use Agreements.

9. Payments/Gifts to Respondents

No payment, gift or remuneration will be provided to respondents.

10. Assurance of Confidentiality

Individuals and organizations will be assured of the confidentiality of their information under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They will be told the purposes for which the information is collected and that, in accordance with this

statute, any identifiable information about them will not be used or disclosed for any other purpose.

Information that can directly identify the respondent will be collected. Information collected will include name, organization, street address, phone number, and e-mail address. All information collected is necessary for the commercial transaction including shipment of the data request and for follow up in the event of a potential violation of the DUA.

The identifiable information collected will be transmitted to the hosting server via an encrypted Secure Socket Layer (SSL) connection. Access to the database housing the identifiable information is accomplished through individual authorized administrative accounts. The server housing the identifiable information is located in a data center owned by Social & Scientific Systems and is located in Ashburn, Va. The datacenter is protected via 24/7 guards at all entrances, video monitoring systems, biometric hand readers, cage locks, and system firewalls.

- The information stored is captured and transmitted over an SSL connection for secure encrypted transmission.
- Access to the database is only permissible at the administrator level and is done so for either a) in order to fulfill the applicants request, b) for system maintenance, or c) in the event of a DUA violation.
- The server housing the system is located in a secure facility with 24/7 guards at the entrance points, camera monitoring systems, biometric hand readers, and cage locks.

The information system has been categorized as a FISMA LOW per the FIPS 199 system categorization form. SSS is in the process of obtaining a Certification and Accreditation utilizing the NIST 800-53 R3 control sets for a low categorization. The minimum controls required for a low system provide adequate assurance that the confidentiality, integrity and availability of the information system are met.

The information collected by the electronic form will be stored in a SQL Server 2008 database. Data stored in the database will remain there indefinitely until requested by AHRQ. SSS performs nightly backups of the database. The backups are encrypted and stored offsite. At the conclusion of the contract, the information system as well as a current copy of the database can be provided to AHRQ by request.

The information system uses a defense-in-depth strategy when it comes to user access. Users are assigned individual credentials along with role based least-privileged user account (LUA). The LUA approach ensures that users follow the principle of least privilege and always log on with limited user accounts. This strategy also aims to limit the use of administrative credentials to administrators, and then only for administrative tasks.

Public users of the information system will establish their credentials upon entry to the system by using their e-mail address as the user ID and specifying their own password. That password will be securely stored (encrypted) in the system's database. The credentials are needed so that a public user could return to an incomplete data request and complete the order. If a user forgets his/her password, the system will reset it and convey that information via e-mail. The public user will have to change that default password upon reentry to the system. Administrative users of the information system will have credentials assigned to them by the system administrator. Various role levels will be defined, each allowing the administrative user permissions to perform specific functions. These functions include examples such as: looking at new data requests, exporting data request information for fulfillment, updating product catalogs, and changing the announcement text when there is information to convey to public users. The system administrator will be able to add and remove administrative users from the system.

The information system will allow applicants to specify a payment option of credit card, e-check, check, purchase order or wire transfer. Information to complete credit card and e-check transactions will be collected by the information system and transmitted securely to a PCI-compliant payment gateway for approval. The payment gateway product will process the transaction and cause the funds to be transferred when the transaction is captured at the time of shipment. While the credit card or e-check information will be collected by the information system, the credit card or e-check information will not be stored in the information system's database. Payments by check, purchase order, or wire transfer will be handled by fax or mail.

11. Questions of a Sensitive Nature

No questions of a sensitive nature will be asked.

12. Estimates of Annualized Burden Hours and Costs

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."

13. Estimates of Annualized Respondent Capital and Maintenance Costs

There are no direct costs to respondents other than their time to submit the online application order form.

14. Estimates of Annualized Cost to the 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

15. Changes in Hour Burden

This is a new collection of information.

16. Time Schedule, Publication and Analysis Plans

Implementation of the online application order system is scheduled to begin in the fall of 2012 and will be on-going.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment A – Federal Register Notice