

SUPPORTING STATEMENT

Part A

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

Version 7/14/2015

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 the Agency 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 seven 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 seven types of databases for public research use:

- 1) The National Inpatient Sample (NIS) is the largest all-payer inpatient care database in the United States, yielding national estimates of hospital inpatient stays. The NIS approximates 20 percent of the discharges from all U.S. community hospitals and contains data from approximately 8 million hospital stays each year. 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 2 to 3 million discharges for children age 20 and younger from more than 3,500 U.S. community hospitals. KID data releases are available every third year starting in 1997.
- 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. NEDS data releases 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 and the District of Columbia that currently participate in the SID. Together, the SID encompasses approximately 96 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 and Services Databases (SASD) contain encounter-level data from ambulatory surgery and other outpatient services from hospital-owned facilities. In addition, some States provide data for ambulatory surgery and outpatient services from nonhospital-owned facilities. Currently, 34 States participate in the SASD. Files are available beginning with data year 1997.

- 6) The State Emergency Department Databases (SEDD) contain data from hospital-owned emergency departments (ED) for visits that do not result in a hospitalization. Currently, 29 States participate in the SEDD. Currently, 32 States participate in the SEDD. Files are available beginning with data year 1999.
- 7) A new database called the Nationwide Readmissions Database (NRD) is planned for release in late 2015. The NRD is designed to support various types of analyses of national readmission rates. This database addresses a large gap in health care data – the lack of nationally representative information on hospital readmissions. The NRD is a calendar-year, discharge-level database constructed from the HCUP State Inpatient Databases (SID).

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 at https://www.hcup-us.ahrq.gov/tech_assist/centdist.jsp. 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 this application include:

- 1) HCUP Application. All persons requesting access to the HCUP databases must complete an application at <https://distributor.hcup-us.ahrq.gov/>. Applications for HCUP State databases require a brief description of the planned research use to ensure that the intended use is consistent with HCUP policies and with the HCUP Data Use Agreement. Paper versions of all application packages are also 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 an 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. An example the DUA for the Nationwide databases is available at <http://www.hcup-us.ahrq.gov/team/NationwideDUA.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, AHRQ must review and approve the applicant’s statement of

intended use to ensure that the planned use is consistent with HCUP policies and with the HCUP Data Use Agreement. 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 primary contractor and subcontractor, Truven Health Analytics 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 quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. (42 U.S.C. 299a(a)(1) and (2).)

2. Purpose and Use of Information

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

1. **Business Transaction:** In order to deliver the HCUP databases and software contact information is necessary for shipping the data on disk (or any other media used in the future).
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 requiring legal remedy.

3. Use of Improved Information Technology

The HCUP online application order form uses a software based data entry process to collect the required information and eliminate the need to print and mail the application form. Automating the HCUP database ordering process (as opposed to the previous paper-based system) has streamlined the ordering process for the public and facilitated more accurate and cost efficient record keeping 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 would not be possible to implement an electronic ordering process and the opportunity to improve Agency efficiency and improve public access to research data.

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 August 20, 2015 for 60 days (see Attachment B).

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 online application ordering 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

The confidentiality of information about individuals and organizations is protected under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). The public is informed of 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 respondents is collected. Information collected includes 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 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 can return to an incomplete data request, to reference their order history, 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.

The information system will allow applicants to specify a payment option of credit card, purchase order or wire transfer. Information to complete credit card 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 information will be collected by the information system, the credit card information will not be stored in the information system’s database. Payments by 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 1,300 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 650 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 \$24,772 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 | 1,300 | 1 | 10/60 | 217 |
| HCUP DUA Training | 1,300 | 1 | 15/60 | 325 |
| HCUP DUA | 1,300 | 1 | 5/60 | 108 |
| Total | 3,900 | na | na | 650 |

Exhibit 2. Estimated annualized cost burden

| Form Name | Number of respondents | Total burden hours | Average hourly wage rate* | Total cost burden |
|-----------------------|-----------------------|--------------------|---------------------------|-------------------|
| HCUP Application Form | 1,300 | 217 | \$38.11 | \$8,270 |
| HCUP DUA Training | 1,300 | 325 | \$38.11 | \$12,386 |
| HCUP DUA | 1,300 | 108 | \$38.11 | \$4,116 |
| Total | 3,900 | 650 | na | \$24,772 |

**Based upon the mean of the average wages for Life Scientists, All Other (19-1099), National Compensation Survey:*

Occupational Employment Statistics, May 2014 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics.

http://www.bls.gov/oes/current/oes_nat.htm#b29-0000

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 |

Exhibit 4. Federal Government Personnel Cost

| Activity | Federal Personnel | Hourly Rate | Estimated Hours | Cost |
|---------------------------|--------------------------|--------------------|------------------------|---------------|
| Data Collection Oversight | 1 (GS-13 Step 5) | 49.50 | 400 | 19,800 |
| Review of Results | 1 (GS-15 Step 5) | 68.78 | 120 | 8,253 |
| Total | | | | 28,053 |

Annual salaries based on 2015 OPM Pay Schedule for Washington/DC area:

<http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2015/DCB.pdf>

15. Changes in Hour Burden

An increase in public use of the system has taken place; however, there has been no change in the estimated hour burden per person.

16. Time Schedule, Publication and Analysis Plans

Implementation of the online application order system began in the fall of 2012 and is on-going.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment A -- Questionnaires/Data Collection Instruments

Data collection instrument is available at <https://distributor.hcup-us.ahrq.gov/>.

Attachment B -- Federal Register Notice