

Supporting Statement for Request for Clearance:

NATIONAL BLOOD COLLECTION AND UTILIZATION SURVEY (NBCUS)

OMB No. 0990-XXXX

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SUPPORTING STATEMENT

NATIONAL BLOOD COLLECTION AND UTILIZATION SURVEY (NBCUS)

This request is for OMB clearance for a new data collection, the National Blood Collection and Utilization Survey (NBCUS). The NBCUS is envisioned as a biennial survey of the blood collection and utilization community to produce reliable and accurate estimates of national and regional collections, utilization and safety of all blood products. The 2007 NBCUS is funded by DHHS and performed by AABB, a member owned 501(c)(3) tax exempt organization whose mission is to advance transfusion safety, and promulgate standards for voluntary compliance and education on key issues affecting blood safety. In previous years a similar survey was performed under the auspices of the National Blood Data Resource Center (NBDRC), a private subsidiary of AABB, with private funding. In 2005 the survey was funded by Department of Health and Human Services (DHHS) and performed by AABB. The questionnaire of the 2007 NBCUS is significantly different from previous versions of the survey and is therefore being submitted to the OMB as a new collection.

In addition to generating national estimates of collection and utilization, the 2007 survey includes new questions to specifically identify and collect baseline data to support efforts towards a real-time biovigilance transfusion safety monitoring system. The 2007 survey also has two new sections on bacterial testing and human tissue transplantation that are of interest to the transfusion medicine community.

The survey questionnaire will be mailed to approximately 3,000 institutions that include hospitals, blood collection facilities, and cord blood banks selected from the American Hospital Association (AHA) annual survey database and AABB member list of

blood collection facilities. The survey includes a core of standard questions on blood collection, processing, and utilization practices to allow for comparison with data from previous surveys. New questions to specifically address emerging and developing issues and technologies in blood collection and utilization are included. Biovigilance is a key theme for the 2007 survey. To that end, questions on transfusion transmitted infections, transfusion associated circulatory overload, acute hemolysis, delayed hemolysis, and severe allergic reactions are included in the survey.

A. Justification

A1. Circumstances Making the Collection of Information Necessary

Under the authority of Section 301 of the Public Health Service Act (42 U.S.C.241), as identified in the 1997 HHS Blood Action Plan (**Attachment A**), and twice in the Advisory Committee on Blood Safety and Availability's (ACBSA) recommendations to the Secretary (**Attachment B**), there is a need to provide national policy makers with current supply and demand data. The ACBSA was established by HHS in 1997 to provide policy advice to the Secretary and the Assistant Secretary for Health. The advice of the committee is partly dependent on the analysis of relevant blood collection and utilization data which is also widely distributed to and used by the transfusion medicine community. To that end, the Office of Public Health and Science (OPHS) is responsible for conducting a biennial cross-sectional national blood products survey. Previous private and government financed versions of the NBCUS have successfully surveyed greater than 90% of the U.S. blood collection and processing

facilities and more than 2,900 hospital based transfusion blood banks in the United States.

As stated in the evolving National Strategic Plan for Blood (final plan will be ready in December 2007), the federal government is charged with developing a blood safety public health monitoring system. The identification and collection of biovigilance data in the 2007 NBCUS will help the government by providing specific data to assist in the implementation of this safety monitoring system.

A2. Purpose and Use of Information Collection

The objective of the NBCUS is to produce reliable and accurate estimates of national and regional collections, utilization, and safety of all blood products – red blood cells, fresh frozen plasma, and platelets, as well as related cellular therapy products. This survey will significantly improve the federal government’s capacity to understand the dynamics of blood supply, safety and availability, and to provide a quantitative basis for assessing strategic and regulatory agendas. An important purpose of the 2007 survey is to help the federal government continue to monitor trends in blood availability since a variety of factors have come to play that have reduced the number of people eligible to give blood and, as stated in the evolving National Strategic Plan for Blood, this information is critical to ensure an adequate supply of safe blood in the United States. In addition to use by the federal government, data collected in this survey will be of practical use to the blood banking and hospital transfusion services communities. In previous years the comprehensive survey report published on blood collection and transfusion related activities has been widely used by the transfusion medicine

community. Broad dissemination of the survey findings through publication of this survey report and scientific papers in peer reviewed journals has significantly benefited not only HHS, but the transfusion medicine community at large by furthering community discussion of key findings. An example of a report from a previous year is included in **Attachment C**. Data from the 1997 and 1999 surveys have been used in testimony before congress. Data from the 2005 NBCUS was used extensively in the preparation of the Transfusion and Transplantation Safety document by DHHS. Additionally the 2005 survey provided baseline information for establishing the Blood Availability and Safety Inventory System (BASIS).

Each question in the proposed survey (**Attachment D**) relates to the analysis objectives detailed in Section A 16. **Attachment E** lists the questions by survey domains and provides justification. The general categories of information to be collected are:

- General information
- Blood collection, processing and testing
- Blood transfusion
- Bacterial testing
- Special procedures and product disposition
- Cellular therapy products
- Human tissue

A3. Use of Improved Information Technology and Burden Reduction

Record-keeping systems of blood banks and hospitals are too diverse to support electronic response to the NBCUS. This survey is envisioned as a paper questionnaire. Efforts made to minimize respondent burden are as follows:

- The questionnaire is divided into color coded sections that clearly identify sections that blood banks/ hospitals/cord blood banks need to complete or skip.
- Appropriate sections of the survey instrument will be mailed to each institution **(Attachment F)**.
- The questionnaire contains easy to read instructions and skip patterns to avoid having respondents answer unnecessary questions.
- The questionnaire contains a glossary of definitions to assist the respondent.

To ensure that the most relevant supply and utilization issues are addressed fully, critical questions from the full survey instrument will be available in the form of a web survey on the AABB website **(Attachment J)**. Institutions either unwilling or unable to participate in the full survey will be asked to respond to this short list of questions.

A4. Efforts to Identify Duplication and Use of Similar Information

Reliable data on blood collection and utilization on a national scale are not available from any other source. While segments of the blood collection industry collect some information, it is often proprietary and not available to the government or the public at large. The 2007 survey will contain the core questions asked on previous national surveys (NBCUS) to allow for comparison of data. In addition, it will also include new questions to identify and collect baseline data to support efforts towards establishing a real-time biovigilance blood safety monitoring system. AABB consulted with its various expert committees, consisting of members who are leading researchers in the field, to identify and develop novel questions that are of interest to the transfusion medicine community.

A5. Impact on Small Businesses or Other Small Entities

Very few of the survey respondents are small hospitals. Hospitals performing less than 100 surgeries are excluded from the sample because they contribute little to either collections or blood product utilization. Nevertheless, to help all institutions complete the survey, a 24 hour toll-free helpline will be provided to answer questions related to the survey.

A6. Consequences of Collecting Information Less Frequently

The NBCUS is administered bi-annually. The rapidly changing environment in blood supply and demand makes it important to have regular, periodic data describing the state of US blood collections and transfusions, for understanding the dynamics of blood safety and availability. These data have become even more crucial with the need to help insure patient safety by monitoring and identifying errors in transfusion medicine and related therapies.

A7. Special Circumstances Relating to Guidelines of 5CFR 1320.5

The proposed data collection is consistent with 5CFR 1320.5. There are no special circumstances applicable to the survey.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

As required by 5 CFR 1320.8(d), the 60-day Federal Register notice was published on December 20, 2006, Vol. 71, pp 76669-76670 (**Attachment G**). No

comments were received in response to this notice. There have been several meetings outside of DHHS to conceptualize and design sections of this survey. Various AABB expert committees such as the Transfusion Transmittable Diseases Committee, the Intra-organizational Task Force on Biovigilance: Working Group, the Tissue Committee, the Cellular Therapies Committee and the Coding and Reimbursement Committee were consulted in the development of the questionnaire. For a complete list of committee members see **Attachment H**. In addition, experts from the Centers for Medicare & Medicaid Services (CMS), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Centers for Disease Control (CDC) and the Health Resources and Services Administration (HRSA) were consulted on relevant sections of the questionnaire.

A9. Explanation of Any Payment or Gifts to Respondents

Respondents will not receive any gifts or payments.

A10. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply to the proposed data collection since respondents are not human subjects, but institutions; and no patient/donor identifiers are collected.

A11. Justification of Sensitive Questions

Information on issues of a sensitive nature involving persons is not being sought. Infectious disease testing results are reported in aggregate only.

A12. Estimates of Annualized Burden Hours and Cost

Burden Hours

The burden for the NBCUS survey is summarized in the table below. Each institution that is asked to complete the survey questionnaire is considered to be a respondent. The respondents to this survey are hospitals, blood collection centers and cord blood banks. The number of eligible respondents is 3,000. It is estimated that each respondent will spend about 180 minutes (3 burden hours) completing the questionnaire. Averaged over a period of three years when this OMB clearance will expire, each respondent will spend 60 minutes (1 burden hour) annually to complete this survey. The hourly burden estimates are based on previous years' experience administering the survey.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Hospitals, blood collection centers, cord blood banks	1,000	1	1	3,000

Burden Cost

The average annualized response burden cost to respondents is estimated to be \$ 96,000 based on an hourly wage of \$32 per hour. The hourly wage estimate is based on the Bureau of Labor Statistics' National Compensation Survey mean hourly wage data for health related occupations in 2005 (**Attachment I**).

Table A12 - 2: Annualized Cost to Respondents			
Type of respondents	Total annual response burden hours	Hourly wage rate	Respondent cost
Hospitals, blood collection centers, cord blood banks	1,000	\$32.00	\$96,000

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record keepers

There are no other capital or start up costs, and no maintenance or service cost components to report.

A14. Annualized Cost to the Federal Government

All survey operations including survey development, data collection, analysis, and preparation of the final report are contracted to the AABB by the government. The total cost of this fixed price contract is \$ 655,856. The annualized cost to the federal government is \$ 218,619.

A15. Explanation for Program Changes or Adjustments

This survey is being submitted for OMB clearance for the first time.

A16. Plans for Tabulation and Publication and Project Time Schedule

The time table for key activities for the 2007 survey is as follows:

Table A 16: Timeline	
5/22/2007	Receive OMB clearance
6/1/2007	Begin data collection for 2007 survey
9/15/2007	End data collection
9/31/2007	close out
10/15/2007	End data processing and create dataset
10/15/2007	Begin data analysis
12/15/2007	Publish final comprehensive report

Statistical tabulations of results for each question will be presented. These will be broken down by institution type, services provided, USPHS region, etc. Selected examples of types of analyses proposed include:

- Analyses of trends in the U.S. blood supply
- Total supply of blood collected in the U.S. broken down by type (Whole blood, Allogeneic, Whole blood autologous, WB directed, RBC apheresis, platelets, plasma etc)
- Total transfusions in the U.S. broken down by type (Whole blood, RBC, platelets, Non-RBC components transfused etc)
- National estimates of all whole blood and blood component units outdated by blood centers and hospitals
- Component modifications – Irradiation, leukocyte reduction by blood centers and hospitals

- Number of repeat reactive and confirmed positive first time and repeat allogeneic donors by infectious disease marker type
- Rates of confirmed positives and false positives by bacterial testing methods
- Number of adverse events (TRALI, TACO, Hemolysis, Allergic reactions etc)
- Number and type of cellular therapy products collected, processed and infused
- Number of human tissue implants/grafts collected
- Number and type of tissue related adverse events
- Departments responsible for human tissue collection

After final validation of results a comprehensive report of findings from the survey will be published. The 2005 Nationwide Blood Collection and Utilization report is provided as an example (**Attachment C**). A similar report will be published at the completion of the 2007 NBCUS survey.

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

Expiration date display exemption is not requested. The OMB clearance number and expiration date will be displayed on the upper right hand corner of the survey.

A18. Exceptions to Certification of Paperwork Reduction Act Submissions

The data encompassed by this survey will fully comply with all guidelines of 5 CFR 1320.9 and no exception is requested to certification for Paperwork Reduction Act Submission.

B. Collection of Information Employing Statistical Methods

The main objective of the National Blood Collection and Utilization Survey (NBCUS) is to provide reliable and accurate estimates of national and regional collections, utilization and safety of all blood products. Estimates by United States Public Health Service Region, by hospital surgical volume, and by establishment type (blood center, hospital) will be required. Since most blood collection occurs in blood collection centers and hospital-based blood banks, while most blood utilization occurs in hospitals, a nationally representative sample of blood collection centers, cord blood banks and hospitals will be required.

B1. Respondent Universe and Sampling Methods

Respondent Universe

The population of inference for the NBCUS will be all blood collection and utilization facilities in the U.S. The target population for the NBCUS will consist of all blood collection centers, cord blood banks and all hospitals subject to certain ownership, service and location criteria. Some practical restrictions were also placed on the target population – specifically, hospitals reporting fewer than 100 inpatient surgeries per year were excluded since they contribute little to either collections or blood product utilization.

Sampling Frame and Sample Design

We used the 2006 (fiscal year 2004) American Hospital Association (AHA) annual survey of hospitals and the AABB institutional membership list together to construct a sampling frame that covers virtually all collection, processing and transfusion of blood.

Hospitals on the AHA file were included in the 2007 NBCUS sampling frame subject to ownership, services, location and surgical volume criteria as follows:

1) Ownership – The AHA ownership (CNTRL) must be:

- Veterans Affairs (45) or
- Other non-Federal
- State (12)
- County (13)
- City (14)
- City-county (15)
- Hospital district or authority (16)
- Church operated (21)
- Other (23)
- Individual (31)
- Partnership (32)
- Corporation (33)

AND

2) Services – The AHA primary service (SERV) must be:

- General medical and surgical (10) or
- Surgical (13) or
- Cancer (41) or
- Heart (42) or
- Obstetrics and Gynecology (44) or
- Eye, ear, nose and throat (45) or

Orthopedic (47) or
Children's general (50) or
Children's orthopedic (57)

AND

3) Location – Located within the 50 United States (or the District of Columbia).

AND

4) Surgical Volume – The hospital must conduct 100 or more inpatient surgeries per year.

Hospitals on the AABB member list that could be matched to the AHA file (i.e., hospitals found on both files) were included in the NBCUS frame and sample subject to the information available in the AHA file and the eligibility criteria described above. Of the 6,072 hospitals on the 2006 AHA file, 4,014 were eligible for NBCUS based on the above criteria.

Following the previous 2005 Nationwide Blood Collection and Utilization Survey, we drew a stratified, single stage sample of blood banks and hospitals with equal probability within stratum. Hospitals on the AHA file were stratified separately from hospitals unique to AABB, blood collection centers and cord blood banks, the latter three groups being selected with certainty. We stratified hospitals on the AHA file by size (annual inpatient surgical volume), and selected hospitals in the larger size strata with certainty. Table B1-1 below gives the total population, sample size and sampling rate for the various types of facilities.

Table B1 – 1 Total population, sample size and sampling rate by type of facility			
Type of Facility	Total Population	Sample	Sampling Rate (%)
Hospitals (AHA)			
100-999 surgeries / year	1,577	525	33.0
1,000-1,399 surgeries/year	368	245	66.0
1,400-2,399 surgeries/year	658	658	100.0
2,400-4,999 surgeries/year	831	831	100.0
5,000-7,999 surgeries/year	344	344	100.0
>=8,000 surgeries/year	236	236	100.0
Hospitals (unique to AABB)	35	35	100.0
Blood Collection Centers*	94	94	100.0
Cord Blood Banks	14	14	100.0
Total Facilities	4,157	2,982	71.7

* Institutions such as the American Red Cross will have their central data repository (ARCNET) reporting for all Red Cross centers. Therefore the number of blood centers sampled does not correspond to the total number of blood centers in the United States.

Based on the 2005 survey, we expect an overall response rate of almost 70% across all types of facilities. Given the overall sample size of 2,982 facilities, we expect a responding sample of about 2,050 facilities.

As with all establishment samples, we anticipate that units on the sampling frame (whether they are sampled or not) can merge with one another, split into multiple units etc. Such events have implications for calculating overall probabilities of selection. We plan to implement procedures that can capture the information relevant to calculating

correct overall probabilities of selection and that also could deal with the phenomenon of sampled units reporting for different organizational levels.

B2. Procedures for Collection of Information

Initial Contact

An introductory letter will be sent from the CEO of AABB (**Attachment K**) to the Director of Transfusion Services of each sampled institution. The letter describes the purpose of the survey, the authority for data collection, and provides a prenotification on the types of information that will be requested on the questionnaire. This will give institutions the opportunity to gather information from 2006 to ease in completing the survey. The introductory letter will have a postage paid tear off section asking for confirmation of the name and contact information of the person who would most likely complete the survey at the specified institution. Verification of the appropriate contact within the selected hospital or blood bank will help increase response rates.

Survey Mailing

Depending upon the type of institution, appropriate sections of the survey instrument (**Attachment F**) along with a prepaid envelope will be mailed. A cover letter co-signed by DHHS and AABB will accompany the survey packet. The cover letter will come from a significant HHS official such as the Assistant Secretary of Health and the CEO of AABB. Since a majority of the transfusing hospitals are AABB members, contact from AABB will help ensure participation.

Follow-up

Two weeks after the initial mailing, follow-up will be made to non-respondents with a postcard. The postcard will provide information on the survey and ask again for participation. In addition, the recipients will be provided with the AABB Survey Helpline information. As noted in Section A5, the toll free helpline will field inquiries related to the survey and will be available 24 hours a day. Two weeks after the second mailing a phone call will be made. The phone call will seek to determine obstacles to completing the survey and offer to help in any way possible. Two weeks following the phone call a letter and a copy of the survey instrument will be sent with a request to complete the questionnaire and return it. Frequently, the first copy of the survey goes astray and it is the subsequent mailing that will stimulate action. As a last step, an abbreviated version of the survey containing critical items will be distributed. This critical item questionnaire will be made available both electronically and in paper form.

Monitoring Data Collection and Quality Control

A survey receipt control system will be used to track and monitor distribution of questionnaires and responses, helping to ensure that actions are taken in a timely manner to maximize response rates. All of the sampled institutions will be entered into an MS Access database to track the mailing, receipt and processing of the questionnaires. When a questionnaire is returned, it will be entered into a table that tracks its processing status. Key to obtaining good response rates and complete data in this type of study is developing a rapport with the individual(s) who will be completing the questionnaire and ensuring that the survey gets to the right person who has the knowledge to respond. The use of the tracking system will assist with this process. In addition, institutions that do not

respond will be offered the opportunity to complete the abbreviated version of the survey. This will help obtain critical information from as many institutions as possible. The tracking system will be the vehicle for follow-up of participation status.

Coding schemes will be used to classify original data from source documents into codes that are machine-readable and appropriate for planned analysis. When an unusual response is recorded that does not appear to fit into the existing coding scheme, it will be reviewed by the data manager to determine how best to handle it. The problem will be passed along to the project director if the data manager is unable to resolve it. COED, a proprietary codebook, and machine-edit PC software will be used to create codebooks and define computerized checks. Manual editing will be performed simultaneously with coding. Manual editing of study documents includes checking for illegible answers, incorrectly followed skip instructions, items not answered, responses outside the ranges of acceptable answers specified in the codebook (range check), responses of an incorrect character length, inappropriate responses and inconsistency between answers. In addition, once initial batches of data have been keyed from study documents, a manual edit, or proofreading, of that data will be completed to ensure that all variables have been keyed into the correct record and column positions.

Verification of coding is an important tool that will be used for quality control. The verification sample of at least 10 percent or higher will be a check of the accuracy of coding and will be carried out by independent recoding. Once the discrepancy or error rate falls to an acceptable level, the verification rate will be cut, but will never be lower than 10 percent.

Prepared and coded survey data will then be keyed and verified. Data entry and verification will be performed using customized PC-based commercial software. Data entry programs will be set up to contain checks for completeness of keyed data, including range checks for precoded items and skip pattern verification. After the raw data files have been edited and updated, they will be converted into SAS data files.

Weighting

Base weights will be calculated for each unit as the reciprocal of its overall probability of selection. These base weights will then be adjusted for nonresponse. We will use sampling strata as initial nonresponse adjustment cells, which can be further refined through the use of Chi-squared Automatic Interaction Detector (CHAID)¹ or other response propensity modeling software to incorporate other variables from the sampling frame that appear related to response propensity. Minimum cell sizes and nonresponse adjustment factors will be considered in the final nonresponse cell definition, in order to avoid unnecessarily large increases in variance due to differential weighting. The use of post stratification raking or calibration to adjust the weights to one or more known or estimated population totals available from the sampling frame, the annual AHA survey data file and the AABB member list will be considered. These adjustments have the effect of increasing the precision of estimates, while matching known population counts.

Imputation

All data items will be checked for internal consistency as part of the data cleaning process and as a prelude to imputation. Missing data will be imputed in continuous (i.e., interval or ratio-level) variables via regression or time series models that take into

¹ Kass, G. (1980). An exploratory technique for investigating large quantities of categorical data. *Applied Statistics*, 29, 119-127.

account previously reported data for the same unit (when available), as well as previously and presently reported data for similar, responding units. Separate imputation models will be used for blood centers and hospitals including volume-related variables (e.g., collection, transfusion and/or surgical counts) as predictor variables. Imputation of nominal or ordinal-level variables, to the extent warranted or desired will be achieved through the use of proprietary Westeck or AutoImpute software, which uses a combination of continuous and categorical data modeling, hot-deck imputation and successive iterations to impute such items, while acknowledging questionnaire skip patterns etc. All imputed data items will be checked for internal consistency using the same routines as the data cleaning process and imputation flags will be provided in the analytic dataset to distinguish imputed from reported values.

B3. Methods to Maximize Response Rates and Deal with Nonresponse

AABB's established relationships in the blood collection and transfusion community, combined with lessons learned from conducting the 2005 survey, will help enhance participation in the 2007 NBCUS. Announcements have already been made at AABB's Annual Meeting in October 2006 to notify the community of the upcoming survey. Presentations of results from 2005 NBCUS were made to further promote the 2007 NBCUS. AABB will use its communication vehicles, distributed daily, weekly and monthly, to help recruit blood centers and member hospitals and to provide updates and information on the 2007 NBCUS. A special section on the AABB website will be dedicated to communication of the 2007 survey as it moves through the 15 month cycle.

For the 2007 NBCUS survey we anticipate that a 70% response rate will be achieved. As described in Section B2, the pre-notification letter asking for confirmation of appropriate contact person at each institution, the follow-up postcard at two-weeks after the initial survey mailing, the telephone call at four weeks, and the follow-up letter and survey mailing at six weeks, along with the toll-free helpline will help us achieve the desired response rate.

Despite the methods described above, we still expect some eligible sampled units to be nonrespondents. We will deal with nonresponse and its potential impact on survey estimates through a combination of weight adjustments and nonresponse bias analysis. As described above (Section B2, Weighting), base weights will be adjusted for nonresponse using CHAID or other response propensity modeling software to incorporate variables from the sampling frame (other than the sampling strata) that appear related to response propensity.

A nonresponse bias analysis will then take advantage of the detailed information available for both responding and nonresponding sampled units from the annual AHA survey data file and the AABB member list to assess the potential for nonresponse bias due to both unit (i.e., complete) and item (i.e., item specific) nonresponse. We will use differences in unit and item response rates across the various detailed data items, both before and after weight adjustments, as a proxy for the potential for nonresponse bias. We will include a summary of the results of this nonresponse bias analysis in technical and analytic reports.

B4. Tests of Procedures or Methods to be undertaken

Given AABB's success in previous years conducting this survey, we believe our plan to pilot the NBCUS survey at two hospitals in the Baltimore-Washington area will be adequate. Consultation was sought from individuals within DHHS, blood center staff familiar with center operations, and experts in transfusion medicine.

B5. Individuals consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The statistician responsible for the survey sample design is:

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ATTACHMENTS

ATTACHMENT A	Blood Action Plan
ATTACHMENT B	ACBSA Recommendations to the Secretary
ATTACHMENT C	2005 NBCUS Survey Report
ATTACHMENT D	2007 NBCUS Survey
ATTACHMENT E	Justification for Survey Questions
ATTACHMENT F	Flowchart of Sections to Complete
ATTACHMENT G	60-Day Federal Register Notice
ATTACHMENT H	Committee Members List (Confidential)
ATTACHMENT I	BLS National Compensation Survey Hourly Rate for Health Related Occupations
ATTACHMENT J	Critical Items Web Survey
ATTACHMENT K	Pre-notification Letter