Supporting Statement
Health and Human Services, Assistant Secretary for Preparedness and Response (ASPR)
HAvBED Assessment to Prepare for Public Health Emergencies

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

On Sept 1, 2009 HHS/ASPR received expedited clearance for data collection in support of the 2009- H1N1 pandemic response. Over the last 6 months, states reported HAvBED data weekly from Sept 09 – Dec 09 (13 weeks), and reported 2x in January. Data collection for H1N1 ended on Jan 22. In all, 15 reporting weeks were completed for HAvBED during the H1N1 response. HHS/ASPR is requesting reinstatement with change to the current clearance to include minor changes to the data elements and collection of data during other national health care responses besides 2009-H1N1 pandemic (see A15).

 As part of the National Response Framework HHS is tasked with mobilizing all national resources to develop and implement strategies to respond to public health and medical emergencies. To achieve this mission enhanced domestic surveillance and clinical data sharing is needed. The data collected during 2009-H1N1 proved to be valuable in assisting HHS to meet its mission.

The Office of the Secretary (OS) is requesting clearance by the Office of Management and Budget to extend and make minor revisions to the HAvBED data collection regarding the status of the health care system. In order to coordinate the provision of Federal public health and medical assistance HHS/ASPR must have current situational awareness of the national health care system that may contribute to a coordinated health and medical response effort. Since September 2009 HHS has collected data on available beds of different types; whether critical care capabilities (e.g. ventilators) are available; whether there are shortfalls with regard to staffing, equipment, supplies and pharmaceuticals; whether the facilities have implemented "surge" strategies to expand capacity and whether their infrastructure has been damaged.

Over the course of the data collection States and other entities provided feedback about ways to re-word the data elements to more accurately measure the variables of interest. The original data elements are shown in ATTACHMENT 1 and the revised data elements are shown in ATTACHMENT 2. To ensure that data about these resources are available and current, the HHS must have the ability to receive the data frequently and in a timely fashion in response to all types of disasters, not just 2009-H1N1 and is requesting that OMB approve an extension and minor revision to the clearance provided on Sept 1, 2009.

Pursuant to section 2811 of the PHS Act, the ASPR serves as the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies. In addition to other tasks, the ASPR coordinates with State, local, and tribal public health officials and healthcare systems to ensure effective integration of

Federal public health and medical assets during an emergency. ASPR's National Hospital Preparedness Program (HPP) awards cooperative agreements to each of the 50 states, the Pacific Islands, and US territories (for a total of 62 awardees) to improve surge capacity and enhance community and hospital preparedness for public health emergencies. These 62 awardees are responsible for enhancing the preparedness of the nation's nearly 6000 hospitals. These awards are authorized under section 391C-2 of the Public Health Service (PHS) Act.

The data collection elements were identified through engagement with subject matter experts. The list of experts can be found at http://www.ahrq.gov/prep/havbed2/havbed2app.htm

The report describes the process used for development of the HAvBED system
http://www.ahrq.gov/prep/havbed2/
that is now operational in the HHS Secretary's Operations Center.

The revised data elements that will be collected through the HAvBED system are outlined in ATTACHMENT 2.

As the system is used for other types of events additional data elements may need to be added to the system to assure situational awareness so HHS can perform its duties under the National Response Framework.

2. Purpose and Use of Information Collection

The overarching purpose of this initiative is to better understand the impact of various disasters (e.g. hurricanes, terrorist events, etc.) on the national health care system and to be able to better respond to the needs of patients in these facilities. During the 2009-H1N1 Pandemic HAvBED was used to track hospital bed availability and measures of stress on the health care system. The average number of states reporting was 46 out of 51 (including District of Columbia).   The max number of states participating was 49 on Jan 06, 2010. The data elements that were tracked trended down over the course of the pandemic and we stopped data collection when we no longer saw indicators of hospital facility stress. The data provided a enhanced situational awareness. For example, the variable "increased demand for pt care services" peaked one week before peak in Influenza Like Illness (ILI) as reported by CDC. This may indicate the value of HAvBED as an early warning system for surge in demand for services within the health care system. The trend data correlates with H1N1 trends for geographic spread and infection load. Reports regarding bed availability and facility stress were provided back to the states and the HHS Regional Emergency Coordinators for validation.

Having the ability to collect HAvBED data during other disasters or events would allow HHS/ASPR to better meet its responsibilities under the National Response Framework. For example, HHS has organic assets that can be deployed to support state requests for assistance to hospitals such as the National Disaster Medical System and Commissioned Corps of the Public Health Service. HHS also coordinates with supporting agencies across the Federal government to support states during public health and medical disasters. For example the Department of Veteran's Affairs has health care personnel who can be deployed to augment hospital staffing. Collecting the data through the HAvBED system will allow us to understand the impact of disasters on the health care system and anticipate state requests for Federal public health and medical support. In this way, HHS will be able to plan for optimal allocation and sharing of limited resources. Ultimately, this effort will result in improved situational awareness and ability to respond in support of hospitalized patients.

3. Use of Improved Information Technology and Burden Reduction

HAvBED is a secured web services data interface. Depending on the nature of the existing systems at the hospitals, the data may be obtained manually or readily available electronically through existing systems. Hospitals will have the option of submitting data via a secured website or allowing specified data held in their own databases to be accessed via a secure data interface. The first option will require the hospital, or the designee, to enter the data at a secure website. With the second option the SOC will passively access the specified data in an existing dataset owned and controlled by the hospital. The HAvBED system was used nationally during the H1N1 response and is now being expanded for data collection in response to other types of disasters.

States would have their own procedures for training staff on how to use their existing systems, so there would not be an additional training burden for learning those systems. For manual data collection using the HAvBED system, personnel have already been trained for the 2009-H1N1 data collection. Only newly hired personnel would require training. The system is easy to use and intuitive. Based on the experience of the system administrator in working with users, training time to learn the HAvBED data entry procedures is no more than one hour. On average it takes 40 minutes of explanation and 20 minutes of hands on practice with the training site.

4. Efforts to Identify Duplication and Use of Similar Information

Each of the approximately 6000 hospital facilities across the country have systems in place to track the availability of resources within their facility on a daily basis, but the robustness and architecture of the systems vary widely. In many hospitals the system is limited to handwritten bed counts that are circulated between hospital departments via telephone or written on chalk boards in a centralized location. Other facilities have elaborate, computer-based systems that allow them to seamlessly share data with sister agencies within a hospital consortia. These systems exist in one form or another, during H1N1 data collection mechanisms were put into place to reliably, uniformly and accurately report these data so they could be aggregated into a national perspective that improved the ability of HHS to support public health and medical preparedness and response during the H1N1 pandemic. We now request to expand data collection to include response to other types of disasters.

5. Impact on Small Businesses or Other Small Entities

This activity does not have a significant impact on small entities, however, small businesses with appropriate capabilities may offer their systems to hospitals to support HAvBED data collection.

6. Consequences of Collecting the Information Less Frequent Collection

For this data collection the situation will dictate how often the data will be collected using the web-based interface known as HAvBED. For a large scale emergency, data will be collected nationally from all 62 HPP awardees to include all 6000 hospitals in HAvBED system. For smaller scale events data collection will be targeted to individual states or regions. Data may also be gathered during exercises. Notifications for data collection are sent to the affected states through the HPP program staff. The data gathered from the hospitals are reported to the HAvBED team in the HHS Secretary's Operations Center to inform situational awareness and national preparedness. During the 2009- H1N1 response nation-wide data were collected weekly for 3 months and then twice monthly for 3 months. Since the HAvBED data collection is activated in response to emergencies it is impossible to predict the exact frequency of data collection. It is anticipated that the minimal data request will be a national data call of all awardees and hospitals once per month throughout the year. If the seriousness of the stress on the hospitals increases up to daily reporting may be requested.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the guidelines. The information may be reported more often than quarterly because of the dynamic nature of disaster response. The data are needed to maintain situational awareness to guide the public health and medical response to this emergency. No proprietary or confidential information will be requested. There will be no patient data collected. Even though no proprietary or patient data will be collected, individual health care facility data will be maintained on a secure server with password protection. Data will be treated in a confidential manner, unless otherwise compelled by law.

8. Comments in Response to the Federal Register Notice/Outside Consultation

We requested and received OMB's emergency review and approval of this data collection effort in August 2009. HHS is now seeking approval from OMB to execute the system for other types of events besides H1N1. The 60-day FRN was published in the *Federal Register on* February 2nd 2010, vol. # 75, pg. # 5330, there were no public comments received.

9. Explanation of any Payment/Gift to Respondents

Neither payment nor gifts will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Data will be associated with the individual health care facility and will be maintained on a secure server with password protection. There will be no patient data collected. Data will be kept private to the extent allowed by law.

11. Justification for Sensitive Questions

No questions of a sensitive nature will be included in the data collection.

12. Estimates of Annualized Hour and Cost Burdens

Depending on the nature of the existing systems at the hospitals, the data may be obtained manually or readily available electronically through existing systems. States would have their own procedures for training staff on how to use their existing systems, so there would not be an additional training burden for learning those systems. For manual data collection using the HAvBED system, personnel have already been trained for the 2009-H1N1 data collection. Only newly hired personnel would require training. The system is easy to use and intuitive. Based on the experience of the system administrator in working with users, training time to learn the HAvBED data entry procedures is no more than one hour. On average it takes 40 minutes of explanation and 20 minutes of hands on practice with the training site.

The frequency of data collection will depend on the number of emergencies and exercises throughout the year. It is not possible to predict the exact number, but it is estimated that data collection will range from 12 per year (once per month) to a maximum of 102 times per year (daily for 3 months, twice monthly for 3 months and monthly for 6 months). The cost model assumes the maximal annual estimated burden, but is likely to be much less than the estimate. Based on past data collection we estimate it will take the 6000 hospitals 1 hour to collect the data. The hospitals will submit their data to their state or territory. We estimate that it will take the 62 states and territories approximately 3 hours to collate the data and submit it to HHS. The salary estimates are based on industry standards.

Estimates Annualized Burden Hours and Cost to Respondents:

Type of Respondent	Number of Respondents	Number of responses per Respondent	Average Burden Hrs. per Response	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Hospital staff (Training)	6000	1	1	6000	$30	$180,000
Hospital staff (data collection)	6000	102	1	6120	$30	$183,600
State/Territory Preparedness staff (training)	62	1	1	62	$45	$2790
State/Territory Preparedness staff (data collection)	62	102	3	18972	$45	$853,740
Total				31,154		$1,220,130

The burden was determined by asking the states that participated in the H1N1 data collection to report who collected the data and how long it took them to gather the information.

13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

There is no additional cost to respondents. Respondents are allowed and encouraged to utilize ASPR Hospital Preparedness Program cooperative agreement funding to develop the systems necessary to collect and report these data to decrease the burden. If system modifications become necessary to collect additional data (as dictated by the disasters experienced) ASPR hospital preparedness cooperative agreement funds can be used.

14. Annualized Cost to Federal Government

Determining the cost based on the worst case scenario when data will be collected daily, total project costs are $1,720,000. Three contract system administrators will be dedicated full time to manage the HAvBED system at an annual cost of $900,000.

In addition to system administration, analytic support is required. The analysis will be conducted by 2 federal GS 14 personnel ($130,000 each) and 2 federal GS 15 personnel ($150,000 each) for a total of $560,000. Report generation and dissemination will require 100% time for 2 GS 14 at a cost of $260,000.

Contract System Administrator Costs:	$900,000 ($300,000 x 3)
Daily data collection (personnel costs) 2 GS 14 100% 2 GS 15 100%	$560,000
Analysis of data (personnel costs) 2 GS 14 100%	$260,000

Total cost to the government in the case that daily collection is necessary: $1,720,000.

Costs would be lowered by 40% to $710,000 if weekly data collection is necessary.

15. Explanation for Program Changes or Adjustments

This is a revision of a prior approved application and there are no significant changes however some of the data elements have been updated based on feedback from the constituents. Attachment 1 shows the original data elements and Attachment 2 shows the new data elements.

For available beds the elements were updated as follows:
- specify adult critical care and medical surgical beds
- remove emergency department beds since they are not counted in the same way as other

hospital beds
-       change terminology to airborne infection isolation from negative pressure isolation
Emergency department diversion status was eliminated because the reviewers felt is was not a reliable measure.

Decontamination status was changed to specify whether mass decontamination was available. If mass decontamination is available, requesting more detail regarding number of lanes available.

Deleted the question on total number of ventilators and clarified the question on number of available ventilators to specify more clearly the kind of ventilator.

Deleted question on how many patients could be managed on rescue therapies and revised the question on patients currently receiving rescue therapies to make the question clearer.

Questions regarding emergency department occupancy were replaced with a question on demands for patient care services.

The question on activating the hospital incident command system was replaced with a question regarding implementing the hospital disaster protocol.

The question on implementing surge strategies was reworded for clarity.

Questions regarding shortages of staff, supplies, pharmaceuticals, protective equipment and ventilator supplies were reworded for clarity and to eliminate the timeframe of 72 hours.

The question on evacuation status was reworded for clarity.

Questions were added to assess whether utilities such as water, heat and sewer are compromised.

A question on medical gases was added.

The question regarding use of back up generators was reworded for clarity.

16. Plans for Tabulation and Publication and Project Time Schedule

Data collection will start as soon as clearance is granted. Data will be analyzed daily by the ASPR staff. Data will be used to inform situational awareness for preparedness and response using descriptive statistics, correlations and trends. Data may be published.

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

Not Applicable.

18. Certifications

There are no exceptions to the certification

B.   Collection of Information Employing Statistical Methods If statistical methods will not be used to select respondents and item 17 on Form 83-I is checked "No" use this section to describe data collection procedures.

1. Respondent Universe and Sampling Methods

The entire universe of 6000 hospitals will be asked to provide data. The 62 States/Territories will be responsible gathering the data from the hospitals within their state/territory and providing it to the HHS Secretary's Operations Center. To obtain national situational awareness, data are need from all hospitals. During the H1N1 response we achieved 63% response rate of hospitals across 46 of 51 states and the DC. We anticipate the response rate will improve as states continue to implement automated data systems using HPP funding.

2. Procedures for the Collection of Information

Data will serve as sentinel indicators of stress on the health care system to inform situational awareness and support the ability of HHS to provide public health and medical assistance to hospitals who need assistance to care for the large numbers of patients who may seek care during disasters. Data to be collected are readily available within the health care system. Depending on the nature of the existing systems at the hospitals, the data may be obtained manually or readily available electronically through existing systems. States would have their own procedures for training staff on how to use their existing systems, so there would not be an additional training burden for learning those systems. For manual data collection using the HAvBED system personnel would need to be trained. The system is easy to use and intuitive. Based on the experience of the system administrator in working with users, training time to learn the HAvBED data entry procedures is no more than one hour. On average it takes 40 minutes of explanation and 20 minutes of hands on practice with the training site.

The actual data collection time for the hospitals is approximately 1 hour and the states will spend approximately 3 hours compiling the information from all of the hospitals in their state/territory. For automated systems the time would be less. These estimates are based on data collection during the H1N1 pandemic. Data will not be tested for statistical significance. Descriptive statistics, trends and relationships will be analyzed.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Data will be used to identify hospitals that are under stress and allow HHS to proactively provide assistance to hospitals in need. Knowing that providing the information will facilitate the provision of Federal public health and medical assistance, hospitals will be likely to provide the information. If hospitals choose to not respond, states/territories every effort will be made to contact the facilities and encourage them to submit the data. If hospitals still do not respond it will decrease our national situational awareness, but will not interfere with our ability to assist those who do respond. Non-responding hospitals will be noted and continued efforts made to contact them through our Regional personnel.

4. Tests of Procedures or Methods to be Undertaken

The HAvBED system has been successfully used during the H1N1 pandemic response. We were able to achieve an average response rate of 63%.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or
Analyzing Data

Data will be collected by the hospital staff and submitted to the states/territories who will submit the information to the HHS Secretary's Operations Center. Data will be analyzed by the HHS ASPR Fusion Cell. The Fusion Cell staff helped design the questions and analysis procedures.

The team leader for the Fusion Cell is:
Jennifer Olsen, 202-205-4729, Jennifer.olsen@hhs.gov

Additional staff in the Fusion Cell who contributed to the analysis plan is
Dina Passman 202-205-4729 dina.passman@hhs.gov

In addition to the subject matter experts who were referenced above an internal review process was conducted with HHS/ASPR staff.

2/2/2021