Supporting Statement
Health and Human Services, Assistant Secretary for Preparedness and Response
HAvBED Assessment for 2009-H1N1 Influenza Serious Illness

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

As part of the National Framework for 2009-H1N1 Influenza Preparedness and Response, Surveillance pillar, HHS is tasked with mobilizing all national resources to develop and implement novel strategies to enhance domestic surveillance and clinical data sharing. A comprehensive assessment of public health and medical data streams has been undertaken by HHS, and information regarding health care system demands and stress has been determined to be woefully inadequate to meet HHS's mission to assist public health and local healthcare systems minimize suffering and maximize lives saved. ASPR is requesting emergency processing procedures for this application because this information is needed immediately to help reduce morbidity and mortality from 2009-H1N1 by providing decision makers with timely, usable information regarding the status of the health care system. The urgent timeline is supported by the fact that Americans are already becoming ill and even dying due to 2009-H1N1 infection, and that numerous countries in the Southern Hemisphere (who are currently experiencing their traditional influenza season) have had a large surge in seriously ill patients. The Southern Hemisphere experience is leading to valid anticipation of many additional seriously ill patients in the US over the upcoming months. During the spring and summer novel H1N1 response in the US, we did not have an adequate understanding of disease severity, health care system resource needs such as ventilators and ICU beds, and did not learn from our collective experiences caring for these seriously ill patients. If we do not develop a national data collection mechanism for seriously ill people infected with H1N1 then we cannot adequately support hospitals to care for these patients.

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. For this data collection the 62 HPP awardees will gather data from the 6170 hospitals[1] using a web-based interface known as HAvBED. The data gathered from the hospitals will be reported to the HHS Secretary's Operations Center. The data elements that will be collected through the HAvBED

1 Source: Centers for Medicare and Medicaid Services, Center for Medicaid and State Operations

system are outlined in ATTACHMENT 1.

Additional data elements may need to be added to the system as the pandemic evolves to assure situational awareness so HHS can perform its duties under the National Response Framework.

In order to coordinate the provision of Federal public health and medical assistance HHS must have current situational awareness of the national health care system that may contribute to a coordinated health and medical response effort. The 62 awardees will collect these crucial data elements from the hospitals in their states/territories and submit to HHS. The data elements relate to this goal by providing information on the stress on the health care system such as whether there are any available beds of different types; whether the emergency departments are overwhelmed; 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. 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. The 62 awardees will have the option of submitting hospital data via a secured website or allowing specified data held in their own databases to be sent via a secure data interface.

We are requesting OMB's emergency review and approval of this data collection effort. ASPR will publish a *Federal Register* notice announcing the initiative on August 20th and allow a 7-day public comment period, with complete package submission on August 28, 2009. Over the course of the following 6 months approval will be sought from OMB to execute the system for other types of events besides H1N1.

2. Purpose and Use of Information Collection

The overarching purpose of this initiative is to better understand the impact of the 2009-H1N1 patients on the national health care system and to be able to better respond to the needs of patients in these facilities. Under the National Response Framework HHS has responsibility for providing Federal public health and medical assistance to states. 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 Corp 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 H1N1 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 with 2009-H1N1 influenza.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected in a standard way through the HAvBED system. HAvBED is a secured web services data interface. 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 tested during exercises with select states and has demonstrated utility to collect information.

4. Efforts to Identify Duplication and Use of Similar Information

Each of the approximately 6170 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. While these systems exist in one form or another, mechanisms currently do not exist to reliably, uniformly and accurately report these data so they can be aggregated into a national perspective that will improve the ability of HHS to support public health and medical preparedness and response to H1N1.

5. Impact on Small Businesses or Other Small Entities

This activity does not have a significant impact on small entities.

6. Consequences of Collecting the Information Less Frequent Collection

The pace of a surging pandemic requires frequent data updates in order to monitor the effects of the pandemic on health care system stress and trends can be monitored. At least weekly and possibly daily data collection will be necessary when the health care system is under stress. Later in a pandemic less frequent collection may be acceptable. When daily collection is no longer of high utility, less frequent collection schedules will be adopted.

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

This request fully complies with the guidelines. The information will be reported more often than quarterly because of the dynamic nature of the H1N1 pandemic flu 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

ASPR published a *Federal Register* notice announcing the initiative on August 20, 2009, and allowed a 7-day public comment period, with complete package submission on August 24, 2009. Over the course of the following 6 months approval will be sought from OMB to execute the system for other types of events besides H1N1.

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.

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 would need to be trained. The system is easy to use and intuitive. The user guide provides information to help people quickly understand how to use the system.

See ATTACHMENT 2 for a copy of the user guide. 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 a pilot test of the system. This cost model assumes daily data collection over 3 months and weekly for 3 months.

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)	6170	1	1	6170	$30	$185,100
Hospital staff (data collection)	6170	96	1	592,320	$30	$17,769,600
State/Territory Preparedness staff (training)	62	1	1	62	$45	$2790
State/Territory Preparedness staff (data collection)	62	288	3	53,568	$45	$2,410,560

*over 6 months

The burden was determined by asking the states that participated in a pilot study 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 in support of the evolving pandemic 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 new data collection.

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 at the end of the flu season.

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 6170 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 a pilot test we achieved 100% response rate. The expected response rate with all states for daily collection is 80%.

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 for H1N1 flu. 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. The user guide provides information to help people quickly understand how to use the system. 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 a pilot test of the system. 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 tested by less than 10 states during exercises. We were able to achieve a 100% response rate when the data manager in the Secretary's Operations Center contacted the states who did not respond within 4 hours of the request for data.

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 are
Amanda Niskar 202-260-5189 amanda.niskar@hhs.gov
Dina Passman 202-205-4729 dina.passman@hhs.go

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

Attachment 1 Data Elements for HAvBED System

Available Beds

- Intensive Care Unit;
- Medical and Surgical (Med/Surge);
- Burn Care;
- Pediatric ICU;
- Pediatrics;
- Psychiatric;
- Emergency Department;
- Negative Pressure Isolation; and
- Operating Rooms;

Emergency Department Diversion Status;
Decontamination Facility Availability
Ventilators:

- Total number of ventilators in each facility (collected only once)
- Number of staffed ventilators available for use
    - Number of available ventilators that are NOT pediatric capable
- Number of patients that could be managed with rescue therapies e.g. ECMO, High Frequency Oscillation, etc.
    - Number that are pediatric capable
- Number of patients related to the event who are currently being managed on rescue therapies
    - # Adults
    - # Children < 18 years
- Does the facility have adequate ancillary ventilator supplies for the next 72 hours?

Facility Stress:

- Total number of beds in each facility emergency department (collected only once)
- Occupancy of each hospital emergency department as of 7PM yesterday?
- Number of patients who left the ED without being seen
- Has the facility activated its incident command structure e.g. HICS? YES/ NO
- Has the facility implemented surge strategies? YES/NO
    - If yes, select all those that apply
      <surge in place strategies e.g. early discharge, cancel elective surgeries, etc.>
      <augmented personnel e.g. extra shifts, volunteers, etc.>
      <established alternate care sites or activated mobile units>
      <requested mutual aid>
- Are staffing shortages affecting your ability to provide services? YES/NO

- Does your facility have enough general medical supplies for the next 72 hours? YES/NO
- Does your facility have enough pharmaceuticals for the next 72 hours? YES/NO
- Does your facility have enough personal protective equipment for the next 72 hours? YES/NO
- Does the facility have sufficient supplies of potable water for the next 72 hours?

Facility Infrastructure (linked with CMS EPRI):

- Operational Status. Select one.
  <Fully operational>
  <Limited operation> <Explain>
  <Closed> <Explain>
- Evacuation Status. Select one.
  <No evacuation>
  <Evacuation in process>
  <Evacuation pending>
  <Evacuation partial> <Explain>
  <Evacuation completed> <Explain>
- Is the facility on back up power? YES/NO
  - If yes, is there sufficient fuel for 96 hours? YES/NO

Attachment 2 HAvBED User Guide