Evaluation of Hospital Preparedness in a Mass Casualty Event (MCE)

SUPPORTING STATEMENT A

Submitted by:

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INTRODUCTION

A. Justification

1. Circumstances Making the Collection of Information Necessary

In accordance with the Centers for Disease Control and Prevention (CDC)'s mission to protect Americans from health, safety and security threats, both foreign and domestic and the mission of CDC's National Center for Injury Prevention and Control (NCIPC) to prevent violence and injuries, and reduce their consequences, NCIPC requests approval of a **new** information collection request for 12 months to allow CDC and its partner, SciMetrika, LLC, to collect the data that will enable them to better understand the current status of hospital preparedness for responding to mass casualty incidents including bombings and non-bombing explosions and disasters that give rise to a rapid influx of large numbers of patients. Additionally, our nation's emergency departments and hospitals are facing enormous daily challenges and are not prepared to respond to the clinical and system challenges posed by mass casualty events. The survey will assess areas in which hospital preparedness may be lacking as targets for future intervention.

There is an ICR from HHS/ASPR already approved with OMB# 0990-0391"The Hospital Preparedness Program," and related to hospital preparedness information. The CDC has coordinated this work with the Chief Emergency Care Coordination Center, and Division Director of Health Systems and Health Care Policy within the Office of the Assistant Secretary for Preparedness and Response. CDC will also coordinate the final report with ASPR.

Once OMB approval has been received, the questionnaire will be administered to a nationally representative sample of US hospitals. An estimated 400 hospitals will be approached and invited to participate, but the sample size of eligible hospitals that agree to participate is estimated to be no more than 320. A sample of 320 hospitals will provide sufficient data of hospital preparedness activities for certain subgroups, such as trauma level or pediatric/adult facility. Data gathered from the survey will be compiled, responses will be analyzed, and a detailed summary of the analysis will be provided.

Sample hospitals came from the AHA hospital directory, which includes trauma level designation and location. Using a random number generator 400 hospitals were chosen at random from four hospital types: 100 community trauma centers, 200 regional resource trauma centers, 50 rural trauma hospitals, and 50 non-trauma centers. The selections were made proportional to the number of hospitals of each type in four regions of the U.S. as defined by the Census Bureau: Midwest, Northeast, South, and West.

2. Purpose and Use of the Information Collection

The overarching goal of this data collection is to assess national capacity of trauma and non-

trauma hospitals to respond to mass casualty incidents involving bombings or non-bombing explosions. Understanding the current capacities will allow the CDC Division of Unintentional Injury Prevention (DUIP), in collaboration with SciMetrika, LLC to develop strategies that address major hospital preparedness gaps. The information gleaned from the survey results are also needed to inform development of a dissemination plan and training manual for improving this capacity. Without the knowledge that the survey will provide, DUIP's effort to develop a thorough and comprehensive guide tailored to hospitals' preparedness needs will not meet the needs of hospitals for improving their levels of preparedness. The purpose of this project will be to (1) develop minimum standards into the assessment tool to enable a review or an evaluation of hospital readiness and (2) develop strategies for dissemination and implementation of the interview tool. A pilot of the questionnaire, sent to 4 respondents, has been completed and necessary adjustments to the overall questionnaire have been made during March of 2014.

3. Use of Improved Information Technology and Burden Reduction

The survey instrument will be implemented as a web-based tool. All respondents will submit responses through the web tool.] An Injury Coordinator will likely be tasked with gathering data from different parts of the hospital. Depending on the hospital, much of the data requested by the survey is likely contained within automated systems. While the initial letter is addressed to the hospital CEO, it is up to each participating hospital on how they wish to complete the survey. We think that it is unlikely that other people will be burdened in the data collection effort. Hospital participants reviewed and completed the survey prior to having one to one discussions with representatives of the survey development team about clarity of the questions, time burden to complete the survey, and suggestions for survey implementation. Participants indicated that a web-based survey will facilitate completion of survey due to the length and extensiveness of the questionnaire. Survey completion requires the collection of data from multiple hospital departments and typically takes an estimated 2 hours including time to gather information from multiple departments and completing the survey. Therefore, a web-based platform will reduce the burden of data collection by allowing the participants to complete the questionnaire over multiple sessions. Computer-generated skip patterns will also be utilized to allow participants to skip non-applicable sections, thus reducing the overall number of questions answered. Screen shots of the web survey are shown in Appendix D.

4. Efforts to Identify Duplication and Use of Similar Information

Prior to development of the survey instrument, DUIP and SciMetrika undertook a number of endeavors to identify previous or current data collection efforts including national surveys on hospital preparedness for mass casualty events focusing exclusively on bombings, non-bombing explosions and natural disasters. These efforts included conducting a review of domestic and international literature on hospital emergency preparedness and surge capacity strategies, consulting with representatives from 17 hospitals and hospital-related organizations, and

reaching out to representatives from the American College of Emergency Physicians (ACEP) and the Office of the Assistant Secretary for Preparedness and Response (ASPR). The outcome of these activities indicated that the planned survey does not duplicate other data collection efforts. Similar efforts to this proposed data collection include the annual National Hospital Ambulatory Medical Care (NHAMC) survey, which is a survey of ambulatory medical care visits to non-institutional, nonfederal, acute care, and short-stay hospitals and the National Association of Public Hospitals and Health Systems (NAPH) survey on Emergency Preparedness in Public Hospitals. However, unlike these surveys, the current survey is not geared towards a specific sector of hospitals (e.g. acute care, short-stay, public hospitals). Moreover, unlike previous or current hospital preparedness surveys, this survey focuses exclusively on mass casualty incidents related to bombing, non-bombing explosions and natural disasters and examines preparedness across multiple hospital functional areas (e.g. pediatrics, radiology, pathology, etc.) as opposed to only general preparedness efforts to mass casualty events. Discussion with participants who completed the cognitive evaluation of the survey also confirmed that there are currently no similar data collection efforts that extensively examine hospital preparedness for mass casualty incident related to bombings, non-bombing explosion and natural disasters at multiple hospital functional-areas. Reviews of prior studies on hospital preparedness, such as the 2006-2007 Emergency Preparedness Study conducted by the National Association of Public Hospitals and Health Systems and the 2008 U.S. Hospital Preparedness for Emergency Response study by the CDC National Center for Health Statistics were completed to minimize duplication of the types of information gathered.

The present CDC's information request is designed to collecting information that was not asked previously in the studies mentioned above. Such information includes the following topics: Hospital Security, Electronic Data Storage, Protection of Evidence, Continuation of Operations, Department Level Response (e.g., blood bank, surgery, morgue, radiology, laboratory, etc.), and Leadership Participation.

The 2008 U.S. Hospital Preparedness for Emergency Response study found that hospital preparedness actions (i.e., emergency response plans, MOUs with burn centers, and drills) for explosive events was less than that of other mass casualty event causes. In addition the 2006-2007 study included only hospitals that are part of the National Association of Public Hospitals and Health Systems (now called America's Essential Hospitals). This hospital sample is primarily urban. The present CDC's information request plans to survey both urban and rural hospitals, and to include differences by hospital type or trauma level designation. Topics not covered by the other studies.

As mentioned before, the OMB approved ICR from HHS/ASPR OMB# 0990-0391"The Hospital Preparedness Program" relating to hospital preparedness information has a similar topic to this collection. The CDC has coordinated this work with ASPR, and will also coordinate the final report with ASPR. Also, the ICR that HHS/ASPR received approval for (0990-0391) is a generic request that is designed to collect information for a specific emergency in a specific community. That ICR is scheduled to expire on 31 March 2015. The present information

request from CDC uses standardized questions and will inform the CDC on overall hospital preparedness in the United States. In this sense, the two information requests are different and not duplicative.

5. Impact on Small Businesses and Other Small Entities

Survey respondents will primarily be the emergency preparedness coordinators/managers for various sizes of hospitals. While most of the organizations are large, some may be small businesses. The survey's requirements do not have a significant impact on small businesses. CDC has kept the sample for this survey to the minimum needed to achieve reliable data. The survey content has also been limited to information essential to research objectives. Furthermore, the survey is voluntary and the time estimate includes time needed to read the study background and consent form and gather requested information. The web-based tool also allows participants to skip sections of the survey that do not pertain to their facility, hence reducing the burden for smaller facilities.

6. Consequences of Collecting the Information Less Frequently

Data collection will occur only once.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A. Federal Register Notice

A 60-day Federal Register Notice was published in the *Federal Register* on April 30, 2014, vol. 79, No. 83), pp. 24440) (see Attachment B). A comment was received (Attachment G), and a standard CDC response was sent.

B. Efforts to consult with persons outside the agency

The CDC Division of Unintentional Injury Prevention (DUIP), in collaboration with SciMetrika, LLC consulted with representatives from 17 hospitals and organizations on availability of survey instruments on hospital preparedness for mass casualty events related to bombings, non-bombing explosions and natural disasters, the need to create a new survey instrument and obtain their input on survey objective, content and recruitment process. The survey instrument was developed by survey methodologists at SciMetrika, LLC. After development of the survey, the instrument was shared with the consultants for review. Several consultants reviewed the instrument and provided comments on the structure, instructions and content of the survey. All received comments were addressed and the survey instrument went through several rounds of review and revision by CDC and SciMetrika staff. Table A.8.1 below provides a list of CDC

staff, SciMetrika staff and external consultants who provided input during the review process. There were no major problems that were not resolved.

Table A.8.1: Survey Design: CDC Staff and Outside Consultation

Organization	Name	Title	Contact Information
CDC	Lisa Garbarino, COR	Public Health Advisor	770.488.1496 / lgt1@cdc.gov
	Mark Faul, PhD, MA	Senior Health Scientist	770.488.1276 / mgf7@cdc.gov
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SciMetrika	Darryl Cooney, MSTAT	Lead Statistician	919.354.5212/ Dcooney@scimetrika.com
	Russ Foushee, PhD	Project Manager	919.354.5272/ Rfoushee@scimetrika.com
	Dena Elimam, MPH	Project Coordinator	404.325.5002/ Delimam@scimetrika.com
	Charles Hallman	Survey Programmer	919.354.5224/ Challman@scimetrika.com
	Ram Jain, PhD	Statistician	404.325.5002/ Rjain@scimetrika.com
	Michael Samuhel, PhD	Technical Advisor	919.354.5263/ Msamuhel@scimetrika.com
Department of Health and Human Services	Gregg Margolis, PhD, NREMT-P	Director, Division of Healthcare Systems and Health Policy	Gregg.Margolis@hhs.gov
Emory University	Alexander Isakov, MD, MPH, FACEP	Executive Director Office of Critical Event Preparedness and Response	404.712.1301/ AISAKOV@emory.edu

American College of Emergency Physicians	Chris Kang, MD, FACEP	ACEP Disaster Medicine Section, WA Chapter President	christopher.s.kang@gmail.com
American Hospital	Roslyne	Director, Policy	202.626.2273/
Association	Schulman, MHA, MBA	Development	rschulman@aha.org
Harbor-UCLA	Amy Kaji,	Medical Director,	310. 222.3500/
Medial Center	MD, PhD	South Bay Disaster Resource Center	akaji@emedharbor.edu
Eastern Virginia	Leonard J.	Professor of Surgery	Weiretlj@evms.edu
Medical School	Weireter, MD, FACS		
HealthEast	Kathryn	Director of Pharmacy	651.232.2343/
Bethesda Hospital	Schultz,		krschultz@healtheast.org
	Pharm. D, FASHP		
University of Texas	Susan John,	Professor of	713.500.7700/
Medical School at	MD	Diagnostic and	susan.d.john@uth.tmc.edu
Houston		Interventional	
		Imaging and	
		Pediatrics	

9. Explanation of Any Payment or Gift to Respondent

Not applicable. No incentives, payments or gifts will be provided to survey participants.

10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by CIO who determined that the Privacy Act does not apply.

All information provided by hospitals will be kept secure to the extent allowed by law. Responses will be reported in summary form only. No personal or specific facility identifiers will be included in either oral or written presentation of the study results. Although data collection will be completed by SciMetrika, LLC, CDC will have complete ownership of all collected data. Any transfer of identifying data between CDC and its survey contractor, is completed using encryption software, so that the data cannot be read by third parties. All identifying information are protected and masked with a pre-coded identification number. Only the survey contractor has access to the identities associated with each number. The survey contractor will protect the web survey application with a password and identification number. Sampled participants can access the web survey *only* with the password and ID assigned to them.

Small analytic cells are also automatically suppressed so that contractors cannot generate frequencies that would allow for identification of an individual provider.

Finally, the survey material includes the following text:

"Data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Responses will be reported in summary form only along with information from the other facilities that participate in the survey. No personal or specific facility identifiers will be included in either oral or written presentation of the study results. Participation in the study is voluntary and your facility is not subject to any penalty if you choose not to provide all or any part of the requested information."

Information being collected is about the organization (i.e. hospital) at which the respondent is employed. CEO names and contact information will be derived from the Hospital Guide while respondent names will be supplied by the CEOs. The selected respondent is chosen as the person who is the hospital's emergency preparedness manager or coordinator as the person most knowledgeable about their hospital's emergency preparedness activities. The name and contact information of the designated responder will be obtained to facilitate primary data collection and for communication purposes during the data collection process only. That information will not be reported or included in any written or oral presentation of the results. Any shared data files will have contact information removed

An NCIPC Determination has been provided (**Attachment F**), which satisfies the project's IRB review requirement.

10.1 Privacy Impact Assessment Information

A web-based survey is the proposed data collection method for this package. The chief executive officers (CEOs) of 400 randomly selected hospitals will be mailed or emailed an invitation letter (see Attachment C) and follow up telephone call to introduce the study (Attachment E), obtain approval to participate in the study and request permission to contact the emergency preparedness coordinator/manager (EPMC) or another person as designated by the CEO. Although 400 hospitals will be invited to participate, an estimated 320 are expected to participate in the study. Those that agree will be sent an introductory letter (see Attachment C) by mail further describing the study and providing a login name and password to the secure survey website to complete the web-based survey (see Attachment D). All data will be collected by SciMetrika, LLC and stored for 6 months past the end of data collection. The consent form is shown as a separate document in Attachment G and as part of the screenshots in Attachment E.

Individuals' contact information will be collected to facilitate data collection and allow for follow up as necessary. This includes their name, work address, work telephone number, and work email address. Respondent race or other demographic information is not being collected. The survey information collected will cover hospital planning, training, and implementation of

preparedness activities for bombing and mass casualty incidents. The study questionnaire is shown in Attachment D. The survey utilizes multiple question formats including yes/no, multiple choices, and open-ended questions.

Individuals will be informed that the survey is voluntary. Individuals will have an opportunity to consent prior to survey completion. Data will be stored on a firewall and password protected system with physical and electronic security controls. The name and contact information of the designated responder will be obtained to facilitate primary data collection and for communication purposes during the data collection process only. That information will not be reported or included in any written or oral presentation of the results.

The contractor, SciMetrika LLC, will employ technical, physical, and administrative controls to protect participants' information. The technical controls being used to safeguard data are user identification and password, firewall, encryption, and an intrusion detection system. Physical controls being used include identification badges, key cards, and video monitoring. Administrative controls include the following:

- There will be a system security plan for this information collection
- There is not a contingency plan for this information collection
- Files will be backed up daily (overnight)
- Backup files are stored off-site
- There will be user manuals (e.g. data collection methods, survey codebook) for this information collection
- Study personnel complete annual training for the protection of human subjects and HIPAA along with training on computer security
- We will adhere to privacy provisions and practices
- Only study personnel will have access to study files
- Digital and non-digital media is sanitized by physical destruction with a licensed, bonded, and insured vendor, thus preventing unauthorized individuals from access or use of the data. Records will be retained and destroyed in accordance with the applicable CDC Records Control Schedule

The process for handling security incidents is defined in SciMetrika's Security Plan. Event monitoring and incident response is a shared responsibility between SciMetrika and the CDC Office of the Chief Information Security Officer (OCISO). Reports of suspicious security or adverse privacy related events should be directed to the component's Information Systems Security Officer, CDC helpdesk, or to the CDC Incident Response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate.

Survey data will be provided to the CDC by SciMetrika, LLC. Data transfer will be encrypted for privacy protection. The data will be used for analysis of preparedness. No other entities will have access to study data. Considering that the focus of the study is collecting data on hospitals' preparedness for mass casualty incidents, it is anticipated that there would be minimal impact on

respondent privacy from the proposed data collection.

11. Justification of Sensitive Questions

The survey does not include any questions of a sensitive nature. All questions are geared towards assessing the hospitals' current preparedness and response capacities. Reported results will be in summary form only and no specific facility identifiers will be included in oral or written presentation of the results. This ensures that participant data will be handled in a secure manner resulting in the anonymity of participating facilities and hence reduces any sensitivity associated with answering questions revealing large gaps in hospital preparedness. Moreover, disclosure of data will not result in liability or competitive disadvantage for hospital organizations.

12. Estimates of Annualized Burden Hours and Costs

Respondent Burden - Screening Activities

- 400 CEOs from sampled hospitals will be screened to ask for participation. They will be mailed an introductory letter, contacted by telephone a few days later and asked if the facility's emergency preparedness coordinator/manager can complete the survey. CEOs will only respond once to the invitation inquiry. Burden estimates from the cognitive evaluation phase indicate that the initial letter takes an average of ten minutes for a CEO respondent to review and respond to the telephone follow up. The total estimated annualized burden for screening activities is 100 hours.
- The emergency preparedness coordinator/manager will complete the main survey. Three hundred twenty emergency preparedness coordinators/managers are expected to complete the survey once. The estimated burden per response is 2 hours, including reading the instructions and gathering information from other hospital departments based on cognitive interviewing conducted with a sample of nine representative respondents. The total estimated annualized burden for surveys is 640 hours.

Note that burden will be placed only on those sampled providers that make a submission. Those who reject a request to participate and do not complete the survey will not be burdened.

Table A.12.1 shows how many respondents are estimated to submit the survey as well as corresponding hour burdens. The tables also include the potential burden on non-responders.

Table A.12.1 Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per	Avg. Burden per	Total Burden Hours
			Respondent	Response (in hours)	110415

CEO	Follow-up	400	1	15/60	100
	Phone Call				
Emergency	Survey	320	1	2	640
Preparedness					
Coordinator /					
Manager					
Total 740					

The bureau of labor statistics estimates that the average annual salary of a CEO is about \$176,840 (http://www.bls.gov/oes/current/oes111011.htm) and emergency management director is about \$64,730 (http://www.bls.gov/oes/current/oes119161.htm). Using the hourly wages of \$85.02 and \$31.12, respectively the estimated cost burden on respondents can be calculated using the average wage per minute multiplied by total time burden.

Table A.12.2 shows how many respondents are estimated to submit the survey as well as corresponding minutes and cost burdens. The tables also include the potential burden on non-responders.

Table A.12.2 Estimated Annualized Burden Costs

Type of	Form	No. of	No. of	Avg.	Total	Hourly	Total
Respondents	Name	Respondents	Responses	Burden	Burden	Wage	Respondent
			per	per	Hours	Rate	Costs
			Respondent	Response			
				(in hours)			
CEO	Invitation	400	1	15/60	100	\$85.02	\$8,502.00
	Letter						
Emergency	Survey	320	1	2	640	\$31.12	\$19,916.80
Preparedness							
Coordinator /							
Manager							
Total							\$28,418.80

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There is no capital, operation, or record keeping costs to respondents.

14. Annualized Cost to the Federal Government

Costs to the federal government is \$162,562.05 in 2013-2014, which includes: updating and testing the secure internet website for the survey, creating and cleaning the sample frame, drawing a clean sample, collecting data, processing data, weighting and analyzing survey data, and reporting survey results. The total anticipated cost to the federal government is comprised of

the participation of the following contractor personnel: health science administrator to assist in project management; public health analyst to assist with recruitment and data collection, data collection and reporting; statistician to assist with data analysis and reporting; and management analyst / consultant to design and manage the project. The total estimated costs including time commitments and the hourly and annual cost of proposed staff are shown in Table A.14.1.

Table A.14.1. Annualized Cost to the Federal Government

Personnel	Number of Personnel	Time Commitment per Year	Hourly Wage	Average Annual Salary
	July 20 –	December 31, 20	13	
Health Science Administrator	1	25.00	\$87.29	\$2,182.25
Public Health Analyst	1	362.50	\$73.39	\$26,603.88
Statistician	1	45.83	\$72.21	\$3,309.38
Management Analyst / Consultant	1	240.00	\$126.85	\$30,444.00
	January	7 1 – July 19, 201	4	
Health Science Administrator	1	35.00	\$90.78	\$3,177.30
Public Health Analyst	1	507.50	\$76.33	\$38,737.48
Statistician	1	64.17	\$75.10	\$4,819.17
Management Analyst / Consultant	1	336.00	\$131.93	\$44,328.48
Material Costs				\$8,960.11
TOTAL				\$162,562.05

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Table A.16.1 provides a draft time schedule we currently use for the survey.

Table A.16.1: Project Time Schedule

Activity Time Schedule

Pilot Survey feedback (4 responses)	March 2014
Sample contact begins	1 month after OMB approval
Telephone follow-ups begins	1 month after OMB approval
Survey field period ends	6 months after OMB approval
Draft reports created	7 months after OMB approval
Final public report available	9 months after OMB approval
Outreach begins after results are released	10 months after OMB approval
Outreach ends	18 months after OMB approval

The project analysis plan will examine the following research questions.

- What are the characteristics of the surveyed hospitals?
- What MCE-related preparedness activities have hospitals undertaken?
- Are there differences in preparedness activities by trauma level and patient population?

To address the first research question, analysis will include descriptive statistics (e.g. frequencies, means, medians, and variance) on survey questions regarding hospital characteristics such as number of beds, trauma level designation, geographic location, and number of staff. Tables A.16.2 and A.16.3 present shell tables as examples to be used for descriptive statistics.

Table A.16.2 Shell Table for Trauma Level Designation

Trauma Level Designation	Frequency	Percent
Adult Hospitals		
Not Designated		
Trauma Level I		
Trauma Level II		
Trauma Level III		
Trauma Level IV		
Trauma Level V		
Trauma Level Other		
Pediatric Hospitals		
Not Designated		
Trauma Level I		
Trauma Level II		
Trauma Level III		
Trauma Level IV		

Trauma Level V		
Trauma Level Other		

Table A.16.3 Shell Table for Average Number of Staffed Beds

Number of Staffed Beds by Unit	Mean	Range
Burn Beds		
Emergency Department (ED)		
Emergency Department (Pediatrics)		
Intensive Care (Medical)		
Intensive Care (Surgical)		
Intensive Care (Neonatal)		
Intensive Care (Pediatrics)		
Medical-Surgical Beds (Adult)		
Medical-Surgical Beds (Pediatrics)		
Obstetrics		
Operating Room		
Post Anesthesia Care		

The second research questions will similarly be addressed using descriptive statistics. Analyses will assess emergency operations planning, emergency supplies, mutual aid agreements, and emergency preparedness training. Table A.16.4 presents a shell table for the frequency and characteristics of Emergency Operations Plans.

Table A.16.4 Shell Table for Frequency of Emergency Operations Plan

Emergency Operations Plan	Frequency	Percent
Hospital has Emergency Operation Plan (EOP)		
EOP is integrated into local emergency preparedness planning		
EOP includes preparedness for MCE		
EOP addresses needs of people with functional and access		
difficulties		
EOP addresses credentialing of volunteer practitioners		
EOP includes procedures to stand up an Incident Command		
System		

The third research question will be assessed by examining differences in preparedness activity levels between hospital groups. Analyses will examine differences based on trauma level, patient population (adult vs. pediatric), and number of beds. Statistical analyses will include chi-square,

t-test, and logistic regression modeling. Specific analyses will be determined by the number of responses received per group. Groups may be combined to allow for sufficient numbers to estimate differences. Table A.16.5 presents a shell table for reporting odds ratios for the existence of an Emergency Operations Plan.

Table A.16.5 Shell Table for Odds Ratios for Existence of Emergency Operations Plan

	N	%	OR	95% CI
Trauma Level				
I				
II				
III				
IV/V/Other				
None (reference)				
Patient Population				
Pediatric (reference)				
Adult				

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.