DOCUMENTATION FOR THE GENERIC CLEARANCE
FOR THE COLLECTION OF QUALITATIVE RESEARCH & ASSESSMENT

TITLE OF INFORMATION COLLECTION: ASPR Medical Supply Chain Interviews

[X] INTERVIEWS
[ ] SMALL DISCUSSION GROUPS
[ ] FOCUS GROUPS
[ ] QUESTIONNAIRES
[ ] OTHER (EXPLAIN:)

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Intended purpose**

   The National Infrastructure Protection Plan provides a framework of sixteen critical sector areas of US assets whose protection from man-made and natural disasters must be planned and prepared for. One of these is the Healthcare and Public Health (HPH) Sector for which the Critical Infrastructure Protection (CIP) program within ASPR OEM's Division of Resilience is the designated lead. CIP is engaged in a variety of methods to protect critical healthcare and public health assets by working with public and private members of the HPH Sector to identify, communicate, and prepare for potential risks in order to develop measures that would minimize their negative impacts.

   It is essential that CIP is able to communicate formally with its stakeholders to gain insights that help us identify and plan for potential crises before they happen. There is a demonstrated risk to the healthcare system if medical supply chains are disrupted. The interviews to be conducted will:

   - Identify existing players in the medical supply chain ecosystem (BARDA, CDC, etc.)
   - Define and quality areas of strength, weakness, redundancy, white space, and potential disruption/change within the ecosystem
   - Inform the preliminary findings to be presented at two stakeholder workshops in March and April 2016

2. **Need for the collection**

   There is a demonstrated need (based on a case study) to improve security and minimize single-source dependency in medical supply chains. These risks are amplified in an increasingly complex healthcare ecosystem with diffused responsibilities for delivery. The interviews will help define, develop, and implement a problem statement and strategy to address medical supply chain security issues, and determine areas where the ASPR could play a role.

3. **Planned use of the data**

   Information obtained through this timely data collection process will help develop findings to be reported during two planned workshops in March - April 2016, during which CIP will work with other ASPR stakeholders to develop/validate a desired future state and translate into actionable strategies for consideration.

4. Date(s) and location(s)

Interviews will be conducted by a contractor team working on a Task Order contract with CIP. The process will begin with the identification of key stakeholders in the medical supply chain ecosystem, and then interviews will proceed over the course of one to two weeks via telephone and in-person. Following the interviews one to two in-person workshops will be scheduled with selected interviewees.

5. Collection procedures

The data collection will be conducted through in-person and telephonic interviews and in-person workshops. Respondents will be informed about the data collection via email requests from the CIP team followed by interview-scheduling requests by the contractor team. The interview process is intended to last one to two weeks. Responses will be voluntary. When the interviews are closed, the ASPR/OEM CIP team and Contractor staff will analyze the data by compiling descriptive statistics and looking for overarching themes in the responses.

6. Number of collections (e.g., focus groups, surveys, and interview sessions)

The collection will consist of face-to-face and telephonic meetings using pre-scripted as well as open-ended questions.

7. Description of respondents/participants

The population will be comprised of a group of approximately 20 - 40 individuals representing a diverse group of federal and private sector stakeholders that CIP and the contractor staff will pre-identify.

The anticipated response rate is 75 percent.

8. Description of how results will be used

The information gathered from the responses will be summarized by CIP and the Contractor team. Contract staff will pull out the main themes from the responses and provide a summary to CIP. CIP and the Contractor will develop goals and agenda topics for the March and April workshops.

9. Description of how results will or will not be disseminated and why or why not

The data from the completed surveys will be directed to appropriate divisions in ASPR to allow for situational knowledge and ability to tailor partnership engagement strategies based on current stakeholder needs.

AMOUNT OF ANY PROPOSED STIPEND OR INCENTIVE – None

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Category of Respondent	No. of Respondents	Average Burden per Response (in hours)	Total Burden Hour
Healthcare practitioners and related occupations	30	1	30 hours

BURDEN COST COMPUTATION

Category of Respondent	Total Burden Hour	Wage Rate	Total
Healthcare practitioners and related occupations (ongoing)	30	$36.54	$1,096.20

OTHER SUPPORTING INFORMATION

REQUESTED APPROVAL DATE: March 25, 2016
NAME OF CONTACT PERSON: Donna Boston, Interim CIP Branch Chief, ASPR/OEM
TELEPHONE NUMBER: 202- 205-8259
DEPARTMENT/OFFICE/BUREAU: HHS/OS/ASPR/OEM/RICD/

Critical Questions

1. Which risks and vulnerabilities are you most concerned about in the current state of the medical supply chain?
2. How would you define success in securing a medical supply chain?
3. What do you see as ASPR's current role in both the pre- and post-crisis medical supply chain?
4. What are your organization's current needs and expectations from ASPR, and are those needs met? If not, what could ASPR be doing differently?
5. What does ASPR specifically do in relation to your organization, and how do you see that relationship fitting into the greater supply chain ecosystem?
6. Which other organizations do you view as most critical to medical supply chain security, and what role are they playing?

Additional Questions

1. Do you believe this map capture the major players in the medical supply chain security ecosystem? If not, who are we missing?
2. When you look at the organizations addressing supply chain security, how are roles defined?
    a. Ex. Do organizations work in specific steps of the supply chain? Are they responsible for getting involved when certain types of products are threatened? Are there general functional roles (coordinator/advisor/implementer)?
3. To maximize effectiveness, how do you think roles should be defined?
4. Ideal state – what does a secure medical supply chain look like for [your organization]?
5. How well do you think different players understand their roles with regards to supply chain security?
6. How well do you think different players understand the roles of other organizations with regards to supply chain security?
7. What is the communication and level of engagement like between members of the ecosystem?
    a. Are there different interactions between different types of players? (Ex. Gov't vs. private sector)
8. What are the key risks threatening medical supply chains?
9. Are there specific steps in the supply chain on which you focus?
10. What are the biggest areas of ambiguity in the ecosystem for supply chain security?
11. How do you define supply chain security for medical goods?

External Organizations

1. How would you characterize your current role in securing medical supply chains?
2. How would you characterize ASPR's role in preparedness and response to medical supply chains?
3. In a stable state, who is your POC for questions regarding medical preparedness and response?
4. In a crisis, who is your POC for questions regarding medical preparedness and response?
5. How would you characterize the level of interaction and communication with the medical preparedness and response community?
    a. In a stable state
    b. In a crisis
6. What, if any, are the coordination groups you regularly work with in the preparedness and response community? What are the purpose of these groups?
7. Keeping in mind lessons learned from previous medical crises, what would you change about how roles and responsibilities are distributed in regards to medical supply chain security?
8. Is there a particular role that you think ASPR would be well-suited to fill?
9. What risks, if any, do you foresee with ASPR taking on this role?
10. Are there are roles that you believe that ASPR should not play? If so, why?

Next Steps and Wrap Up

1. Is there anything we haven't talked about yet that you feel would be important for us to consider as we attempt to get a holistic view of the medical supply chain ecosystem?