Supporting Statement A for Paperwork Reduction Act Generic Information Collection Submissions for
"Administration for Strategic Preparedness and Response—Office of Strategy, Policy, Planning, and Requirements Generic Clearance for the National Strategy for a Resilient Public Health Supply Chain"

Paperwork Reduction Act (PRA) Compliance; Request for Generic Clearance

Department of Health and Human Services

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A. Justification

1. Circumstances Making the Collection of Information Necessary

As directed by Executive Order 14001 (Attachment A), The National Strategy for a Resilient Public Health Supply Chain (The National Strategy) provides a strategic approach to design, build, and sustain a long-term capability in the United States to manufacture supplies for future pandemics and biological threats. The Administration for Strategic Preparedness and Response (ASPR) at the Department of Health and Human Services (HHS) is leading an interagency team in implementing the National Strategy and is requesting a generic clearance for purposes of implementation to: gain a better understanding of the public health supply chain; develop future strategic goals and recommendations for building immediate and long-term resilience through increased visibility, agility, and robustness in the public health supply chain to prepare for and mitigate future public health emergencies; and to ensure ASPR, HHS, and the broader U.S. government have current data and information to inform program and policy decision-making. We seek to obtain Office of Management and Budget (OMB) approval of a generic clearance to collect feedback on public health supply chain program and strategic issues. By feedback, we mean information that provides useful insights on perceptions and opinions but are not statistical surveys that yield results that can be generalized beyond the population of the study.

The following federal Departments and Agencies compose the National Strategy interagency implementation team. Additional Departments and Agencies may be added to the team as needed as implementation activities continue:

- HHS
  - ASPR
  - Centers for Disease Control and Prevention
  - Food and Drug Administration
  - Office of the General Council
  - Office of Global Affairs
- Department of Homeland Security
- Department of Commerce
- Department of Defense
- Department of Energy
- Department of Labor
- Department of State
- Department of Veterans Affairs
- Office of Management and Budget
- U.S. Environmental Protection Agency
- U.S. Trade Representative

ASPR leads the nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies. ASPR collaborates with hospitals, healthcare coalitions, biotech firms, community members, state, local, tribal, and territorial (SLTT) governments, and other partners across the country to

improve readiness and response capabilities. HHS/ASPR is working with the White House and with HHS and interagency partners to launch a multiyear implementation of over 20 efforts involving the identification and coordination of measurable activities across the U.S. government, SLTT jurisdictions, and private sector partners. Each of these action items must engage with SLTTs, the private sector, and other stakeholders to obtain information to create further plans, policies, and guidance to enhance the nation's public health supply chain.

This collection of information is necessary to enable ASPR and the National Strategy interagency implementation team to receive feedback in an efficient, timely manner, in accordance with ASPR's mission and the National Strategy's goals to build immediate and long-term resilience through increased visibility, agility, and robustness in the public health supply chain to prepare for and mitigate future public health emergencies.

Formative research and assessment are the main objectives of the activities included in this clearance. The participants will include, but not be limited to, SLTTs, trade groups and associations, mixed cross-sector audiences, non-governmental organizations, manufacturers, academia, healthcare providers and facilities, and local communities, labor unions, workforce training providers, organizations, and state and local workforce boards.

2. <u>Purpose and Use of Information Collection</u>

ASPR and the National Strategy interagency implementation team will collect, analyze, and interpret information gathered through this generic clearance to support efforts to strengthen public health supply chains and improve understanding of current programs, policies, and services under the public health supply chain. The purpose is to obtain and better understand broad and diverse perspectives on the public health supply chain, engagement, health care and other emerging issues, and promising practices by innovative programs or organizations funded by HHS. ASPR and the National Strategy interagency implementation team will use the information to develop further plans, policies, strategies, and guidance to enhance the nation's public health supply chain.

Under this clearance a variety of instruments will be used. Though the exact nature of the questions and samples is currently undetermined, ASPR and the National Strategy interagency implementation team expects that they will include but not be limited to issues related to:

- Global partnerships
- External stakeholder engagement and coordination
- Governance
- Innovation
- Manufacturing and Industrial Base Expansion investments
- Regulations, policy, and standards
- Workforce development

- Stockpiling, allocation, and coordination
- Trade policy & Buy American

The data collection methods employed will vary based on the issue being examined, but examples include stakeholder meetings, surveys, town hall meetings, workshops, and working groups. The information collected will provide insights into stakeholder perceptions, experiences, and expectations. These collections will allow for ongoing, collaborative, and actionable communications between HHS/ASPR and the National Strategy interagency implementation team and their stakeholders. If this information is not collected, vital feedback from stakeholders on public health supply chain issues will be unavailable or available in a very limited way (fewer than 10 respondents).

The Agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- Information gathered may not directly inform influential public policy decisions as defined by OMB. Information may also inform the development of ASPR's and the National Strategy interagency team's future intramural and extramural research projects, which could in turn inform influential public policy decisions;[1]
- Information collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the broader population;
- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the federal government;
- The collections do not raise issues of concern to other federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future; and
- With the exception of information needed to provide renumeration for participants of focus groups and cognitive laboratory studies, personally identifiable information (PII) is collected only to the extent necessary and is not retained.

If these conditions are not met, the Agency will submit an information request to OMB for approval through the normal PRA process.

To obtain approval for a collection that meets the conditions of this generic clearance, a standardized form (Attachment C) will be submitted to OMB along with supporting

[1] As defined in OMB and agency Information Quality Guidelines, "influential" means that "an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions."

documentation (e.g., a copy of the focus group guide). OMB will respond to the submission with questions or approval within 14 business days, or as appropriate given the nature of the submission.

The types of collections that this generic clearance covers include, but are not limited to:

- Interviews
- Focus groups/working groups
- Questionnaires
- Town hall and other stakeholder meetings
- Electronic data transfer

HHS/ASPR has established a manager/managing entity to serve for this generic clearance and will conduct an independent review of each information collection to ensure compliance with the terms of this clearance prior to submitting each collection to OMB.

3. Use of Improved Information Technology and Burden Reduction

ASPR does its best to ensure we are requiring the least amount of burden when collecting information from the public. To the extent possible, we always strive to collect information electronically and/or use online collaboration tools to reduce burden.

4. Efforts to Identify Duplication and Use of Similar Information

ASPR collaborates and coordinates routinely with all parts of HHS and other federal agencies. We do our best to ensure no similar data are gathered or maintained by other parts of HHS or are available from other sources known to us. To the extent possible, ASPR collaborates with internal and external partners to ensure there is not duplication of information collected.

This information collection does not duplicate any other research methods being conducted by ASPR or at HHS in general, or by any of the Departments and Agencies that compose the National Strategy interagency implementation team. ASPR typically looks at cross-cutting issues that may involve several agencies within HHS to provide a departmental view and coordination. This clearance will improve the quality of ASPR's and the National Strategy interagency implementation team's public health supply chain research and assessment as well as providing a more efficient means for conducting more rigorous research and assessment. To the maximum extent possible, we will make use of previous information by reviewing results of previous research projects on relevant public health supply chain issues before we attempt to revise interview guides, questionnaires, and other tools using additional field work sought under this clearance.

5. Impact on Small Businesses or Other Small Entities

Small business or other small entities may be involved in these efforts, but ASPR and the National Strategy interagency implementation team will minimize the burden of

information collections approved under this clearance by sampling, asking for readily available information, and using short, easy-to-complete information collection instruments whenever possible.

6. **Consequences of Collecting the Information Less Frequent Collection**
This clearance informs public health supply chain research and assessments for dynamic public health, human service, and healthcare issues, changing trends in population health, and new health threats. If we do not continue this mechanism, ASPR and the National Strategy interagency implementation team will be limited in their ability to solicit feedback from broad and diverse public health supply chain experts and stakeholders, impacting our ability to provide up-to-date information from external stakeholders to HHS leadership.

7. **Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**
There are no special circumstances. The information collected will be voluntary and will not be generalizable.

8. **Comments in Response to the Federal Register Notice/Outside Consultation**
A 60-day Federal Register Notice was published in the Federal Register on May 18, 2022, vol. 87, No. 96; pp. 30230-30231 (Attachment B). There were no public comments.

9. **Explanation of any Payment/Gift to Respondents**
HHS will not provide payment or other forms of remuneration to respondents of its various forms of collecting feedback. If it becomes evident that remuneration is necessary, ASPR will provide $40 or less per respondent for in-person information collection, ASPR will include a statement to this effect and any other associated documentation as necessary in information collection requests under this mechanism. If evidence suggests that it is necessary to provide remuneration in excess of $40 per respondent, ASPR will provide a statement to this effect and will provide justification in the form of empirical evidence that the specified remuneration is necessary.

10. **Assurance of Confidentiality Provided to Respondents**
ASPR does not anticipate the Privacy Act will apply to any of our data collections under this generic mechanism. If the Privacy Act applies to a collection, ASPR will provide a Privacy Act statement, a System of Record Notice (SORN), or any other associated documentation as necessary. If a confidentiality pledge is deemed useful and feasible, the Agency will include a pledge of confidentiality that is supported by authority established in statute or regulation, that is supported by disclosure and data security policies that are consistent with the pledge, and that does not unnecessarily impede sharing of data with other agencies for compatible confidential use. If the agency includes a pledge of confidentiality, it will include a citation for the statute or regulation supporting the pledge. Most of the information collections under this mechanism have not collected personally identifiable information or information of a personal or sensitive nature.

11. Justification for Sensitive Questions

No questions will be asked that are of a personal or sensitive nature.

12. Estimates of Hour and Cost Burden over Three Years

A variety of instruments and platforms will be used to collect information from respondents. The burden hours requested (358,934 over three years) are based on the number of collections we expect to conduct over the requested period for this clearance. To calculate the annualized burden to respondents, we assumed the number of respondents and number of responses and response hours needed.

12A. Estimated Burden Hours Over Three Years

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Private sector companies, SLTT, Trade groups and associations, NGOs, Manufacturers, distributors, Academia, Healthcare delivery providers/facilities, Public, USG Supply chain inventory holders, Biopharmaceutical industry, Biotechnology development companies, Communities, GPOs, standards development organizations, logistics, third party contractors, purchasing organizations, professional associations/societies, Mixed cross-sector audience, labor unions,	Informed consent	32800	1	5/60	2734
	Demographics standardized questionnaire with decision logic allowing some questions to be omitted	32800	1	15/60	8200
	Cognitive questionnaire	6000	1	8	48000
	Formative interviews and focus groups	6600	2	4	52800
	Town halls and public meetings	10200	2	8	163200
	Supply chain questionnaires	1000	156	30/60	78000
	Knowledge-based questionnaires	6000	1	30/60	3000
	Interviews and focus groups	3000	1	1	3000

workforce training providers, organizations, state and local workforce boards					
Total Burden Hours Over Three Years					358,934

12B. Cost Burden Estimate Over Three Years

The annualized costs to respondents for the burden hours associated with this generic information collection varies depending on the type of respondent for each form. As there are no specified respondents for each form in the burden table above, the hourly wage rate per respondent will vary from $0.00 for members of the public who are participating outside of a professional capacity to $64.71 for stakeholders representing purchasing organizations.[2] As such, the total respondent costs for all form types in the table below range from $0.00 to $23,226,620 over three years.

Exhibit A.12.B. Cost to Respondents Over Three Years

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Informed consent	2734	$0.00 - $64.71	$0.00 - $176,918
Demographics standardized questionnaire with decision logic allowing some questions to be omitted	8200	$0.00 - $64.71	$0.00 - $530,622
Cognitive questionnaire	48000	$0.00 - $64.71	$0.00 - $3,106,080
Formative interviews and focus groups	52800	$0.00 - $64.71	$0.00 - $3,416,688
Town halls and public meetings	163200	$0.00 - $64.71	$0.00 - $10,560,672
Supply chain questionnaires	78000	$0.00 - $64.71	$0.00 - $5,047,380
Knowledge-based questionnaires	3000	$0.00 - $64.71	$0.00 - $194,130
Interviews and focus groups	3000	$0.00 - $64.71	$0.00 - $194,130
Total	358934	$0.00 - $64.71	$0.00 - $23,226,620

13. <u>Estimates of other Total Cost Burden to Respondents or Recordkeepers/Capital Costs Over Three Years</u>

No costs are anticipated, but individual projects will provide estimates as identified.

[2] Hourly wage rates are based on the U.S. Bureau of Labor Statistics, according to which the national average hourly wage for purchasing managers is $64.71. Of all respondent types included in the burden table, purchasing managers had the highest estimated average hourly wage. https://www.bls.gov/oes/current/oes113061.htm.

14. Annualized Cost to Federal Government

Implementing the National Strategy includes over 20 lines of effort (LOEs), each requiring different resources. The estimated cost to the federal government per LOE, which assumes at least one project officer (GS-13/14, 0.5 FTE)[3] and at least two project support staff members (GS-9/11, 0.5 FTE),[4] is approximately $96,337 annually, for an estimated cost of $2,023,077 annually across all LOEs, and an estimated total cost of $6,069,231 for all LOEs over the period of three years. An estimated cost for all activities under this generic clearance is listed below, but detailed costs, including additional operational expenses, cooperative agreements or contracts, and/or any other specific resources required for National Strategy implementation will be submitted with each individual collection request.

Expense Type	**Expense Explanation**	**Estimated Annual Costs (dollars)**
Direct Costs to the Federal Government per LOE		
	Project Officer (GS-13/14, 0.5 FTE)	$44,297
	Project Support Staff (GS-9/11, 0.5 FTE)	$26,020
	Project Support Staff (GS-9/11, 0.5 FTE)	$26,020
	Subtotal, Estimated direct costs per LOE	$96,337
	ESTIMATED ANNUAL COST TO THE GOVERNMENT FOR ALL LOES	**$2,023,077**

[3] Estimated costs were calculated by averaging and then halving the Step 1 salaries of GS-13 and GS-14 positions, per the Salary Table 22- GS available on the OPM website: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/22Tables/html/GS.aspx.

[4] Estimated costs were calculated by averaging and then halving the Step 1 salaries of GS-9 and GS-11 positions, per the Salary Table 22- GS available on the OPM website: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/22Tables/html/GS.aspx.

	ESTIMATED TOTAL COST TO THE GOVERNMENT FOR ALL LOES OVER THREE YEARS	**$6,069,231**

15. Explanation for Program Changes or Adjustments
This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule
Individual data collections under this generic approval will be time-limited and generally conducted only once, except in the cases of individual interviews conducted during pilot testing of interventions where respondents may have to be approached several times on the same or similar topic under evaluation. No single data collection activity will take longer than one year to complete from inception of information collection to the first report of findings. Proposed timelines and plans for tabulation and publication, if applicable, will be submitted with each individual data collection request.

17. Reason(s) Display of OMB Expiration Date is Inappropriate
We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions
These activities comply with the requirements in 5 CFR 1320.9.