



TRIDENT HEALTH LAW

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VIA: www.reginfo.gov/public/do/PRAMain

Office of Information and Regulatory Affairs

Office of Management and Budget

Washington, D.C. 20503

RE: Comments on Information Collection Request — Document Identifier OS-0990-0488-30D; Title: *Ensure a Strong Public Health Supply Chain Through Streamlined Oversight and American Priorities*

To the Office of Information and Regulatory Affairs:

Trident Health Law submits the following comments on the above-referenced Information Collection Request (ICR) published in the Federal Register on February 27, 2026. The ICR was submitted by the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS) and seeks a three-year extension of OMB Control Number 0990-0488. Trident Health Law is law firm with focus on healthcare regulatory compliance, policy advisory, and healthcare transactions, and has several clients that will be impacted by this proposed ICR. We respectfully urge OMB to withhold approval of this clearance in its current form for the reasons set forth below.

I. The Proposed Collection Does Not Qualify for Generic Clearance

The proposed collection is presented as an extension of a "generic clearance" under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. §§ 3501–3521. However, the scope and nature of the activities described in the ICR exceed the boundaries of what a

generic clearance is designed to authorize, and OMB should require HHS/ASPR to obtain a specific, program-specific clearance instead.

Generic clearances exist to permit a limited category of low-burden, noncontroversial information collections—primarily customer satisfaction surveys, public opinion polls, and similar voluntary, anonymous, feedback-oriented collections that pose minimal burden and risk. OMB's own guidance makes clear that generic clearances are appropriate only for collections that: (1) share a common subject matter or method; (2) individually impose minimal burden; and (3) do not generate data used for regulatory or significant policy decisions. *See* OMB, Supporting Statement Guidelines; OMB, Federal Collection of Information (5 CFR Part 1320).

The proposed collection here departs materially from that model. The ICR describes a broad, multi-year, cross-sectoral information collection apparatus designed to support significant federal policy objectives—including the implementation of the Strategic Active Pharmaceutical Ingredients Reserve (SAPIR), assessments under Section 232 of the Trade Expansion Act of 1962, and coordination of stockpiling plans among state, local, tribal, and territorial (SLTT) jurisdictions. The collection encompasses:

- Cognitive questionnaires (avg. 8 hours per response);
- Formative interviews and focus groups (avg. 4 hours per response, 2 responses per respondent);
- Town halls and public meetings (avg. 8 hours per response, 2 responses per respondent);
- Supply chain questionnaires (avg. 0.5 hours per response, but 156 responses per respondent annually);
- Interviews and focus groups; and
- Instrumented information collection.

These are substantive, policy-relevant, and in some cases recurring data collections—not the kind of low-stakes, one-time, feedback-oriented surveys that generic clearances contemplate. The use of a generic clearance mechanism to authorize data collection in support of national security-linked supply chain policy, pharmaceutical reserve planning, and regulatory assessments is a misapplication of the generic clearance process. OMB should require ASPR to submit a specific, program-level ICR with a full

Supporting Statement A and Supporting Statement B, including a detailed methodology justification and independent burden analysis.

II. The Estimated Burden Hours Are Significantly Underestimated

Even setting aside the generic clearance issue, the proposed burden estimates are implausibly low and appear to undercount both the per-response burden and the total number of affected respondents. The ICR estimates a total burden of 358,824 hours over three years. For the following reasons, this figure likely understates true burden by a considerable margin.

A. Cognitive Questionnaires

The ICR estimates that 5,990 respondents will complete a cognitive questionnaire averaging 8 hours per response—a total of 47,920 hours. Cognitive testing instruments of this type, particularly those used for population health or supply chain research, routinely require respondents to review and engage with complex technical content before responding. For sophisticated respondents (*e.g.*, healthcare executives, public health officials, or supply chain managers), 8 hours may be sufficient for the survey instrument itself, but does not account for the time required to gather supporting data, consult internal records, or coordinate with colleagues (who will thus also have reporting burdens that are not captured in the proposed ICR) before responding. A realistic burden estimate should incorporate these pre-response activities.

B. Supply Chain Questionnaires

The estimate of 0.5 hours per response for supply chain questionnaires, at 156 responses per respondent annually, implies that 1,000 respondents will complete a 30-minute questionnaire more than three times per week, every week, for three years—yielding 78,000 burden hours. The frequency of 156 responses per respondent per year is extraordinary and is not adequately explained or justified in the ICR. If accurate, the cumulative burden per respondent is 78 hours per year, which is a substantial ongoing commitment. The aggregate burden from this single collection type alone—78,000 hours—warrants far greater scrutiny and justification than a generic clearance affords.

C. Formative Interviews, Focus Groups, and Town Halls

The ICR accounts for direct participation time in these activities, but does not appear to account for preparation time, travel time (for in-person events), review and follow-up time, or internal coordination costs that respondents—particularly from SLTT agencies and private sector entities—will incur. For institutional respondents, the marginal cost of participation in multi-hour town halls and focus groups is often far greater than the time spent in the session itself. OMB's PRA guidance requires that burden estimates capture "the time, effort, and financial resources necessary to respond"—including time to gather information and prepare a response. The current estimates appear to capture only direct response time.

D. Overall Methodological Concerns

The ICR notes that no comments were received during the initial 60-day comment period. This is of concern given the scope and ambition of the proposed collection. The absence of public comment may reflect insufficient outreach to affected stakeholder communities rather than genuine consensus that the proposed burden is reasonable. We urge OMB to require ASPR to conduct a meaningful pre-clearance stakeholder engagement process before this clearance is approved.

III. Recommendations

For the reasons stated above, Trident Health Law recommends that OMB:

- Decline to approve this ICR under the generic clearance process and require HHS/ASPR to submit a specific, program-level clearance request with a full Supporting Statement A and B;
- Require ASPR to provide a revised and independently validated burden estimate that accounts for pre-response preparation, institutional coordination costs, and the extraordinary frequency of the supply chain questionnaire;
- Require ASPR to explain and justify the basis for the 156-responses-per-respondent figure for the supply chain questionnaire; and
- Require ASPR to conduct a meaningful pre-clearance engagement with affected stakeholder communities—including SLTT agencies, healthcare providers, private sector supply chain participants, and trade associations—before any clearance is granted.

Trident Health Law appreciates the opportunity to submit these comments. We are available to discuss any aspect of these comments at the OMB's convenience.

Respectfully submitted,

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