

Supporting Justification Statement for HHSAR 311.7300

1. Circumstances Making the Collection of Information Necessary

Performance of HHS mission requires the support of contractors. In some circumstances, depending on the requirements of the specific contract, the contractor is tasked to gather data that involves requesting this data from sources outside of HHS (i.e. the public). In those circumstances HHSAR 52.211-3 Paperwork Reduction Act is included in the contract and prevents the contractor from initiating the solicitation of information from third parties unless and until a proper clearance from OMB has been obtained, specific to that data collection. This clearance covers the data collection necessary to determine what information should be collected in order to prepare the contract-specific OMB clearance request as required by the Paperwork Reduction Act or 1995 44 USC 3501.

2. Purpose and Use of Information Collection

Each collection would be contract-specific. They include surveys, questionnaires and interviews. The information will be collected from each contractor required to prepare such requests.

3. Use of Improved Information Technology and Burden Reduction

All data submitted by contractors (100%) is requested to be submitted electronically.

4. Efforts to Identify Duplication and Use of Similar Information

The purpose of a contract requirement to gather additional data would only occur once a determination has been made that the data does not otherwise exist. Because each collection will be contract specific, there should be no duplication of any such request.

5. Impact on Small Businesses or Other Small Entities

The requirements of the Paperwork Reduction Act apply regardless of the size of the contractor. The data being requested is being provided by the contractor pursuant to the contract requirements. Any burden would be the same for any size entity and is necessary for performance of the specific contract. The contract price would reflect the contract requirements. Thus there is no additional burden or excessive burden placed on small businesses.

6. Consequences of Collecting the Information; Less Frequent Collection

Collection efforts by contractors are in response to specific contract requirements that are drafted to address specific missions of HHS. In most cases each contract would have a single collection for purposes of gathering the data necessary for contract performance. In certain research contracts, the research requires a defined schedule for successive data collection efforts. In most cases these requirements would be grouped within the research protocol and should result in a single request for clearance under a single approval. Thus even when the contractor must conduct a series of collection activities under the contract, the requirement on the contractor to obtain a clearance for their contract performance would be a single data collection at the outset of the contract.

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

- There are no special circumstances related to collection of this information.
- There are no requirements to report information to the agency more often than

quarterly.

- Generally contractors will be required to provide the requisite information after award and more than thirty days after award. In certain specific situations within HHS emerging requirements could dictate a quicker turn-around in order to allow the research to progress. In those cases the data might be required to be submitted with proposals or shortly after contract award. These situations would be the exception to the general practice and would be justified within the contract file documentation.
- Contractors will not be required to submit more than an original and two copies of any document. In virtually all cases an electronic submission is sufficient.
- Contract laws and regulations dictate record retention requirements for contracts. Any retention of records by the contractor would be subject to privacy and other laws and regulations and would be addressed in the request for clearance that is submitted on behalf of the contractor for the specific contract requirement.
- It is not expected that any contractor would be required to use a statistical data classification that has not been reviewed and approved by OMB; any assertion of confidentiality in the data would be covered by contract clauses, specifically those found in FAR Part 27 and HHSAR Part 327. Likewise contract clauses would address security requirements and the government's rights to further use the data.
- The protection of contractor proprietary, trade secret, or other confidential information and the government's right to use that data are covered by contract-specific clauses.

8. Comments in Response to the Federal Register Notice/Outside Consultation

A 60-day Federal Register Notice was published in the *Federal Register* on March 2, 2015, vol. 80, No. 407; pp. 11273-74 (see attachment). No public comments related to data collection were received.

9. Explanation of any Payment/Gift to Respondents

Contractors are reimbursed pursuant to the terms of each respective contract. No gifts are ever involved.

10. Assurance of Confidentiality Provided to Respondents

The release of any information provided by a contractor is governed by the provisions of the Freedom of Information Act (5 USC 552) (FOIA).

11. Justification for Sensitive Questions

No sensitive questions are asked of contractors under this data collection.

12. Estimates of Annualized Hour and Cost Burden

12A. Estimated Annualized Burden Hours

Annual reporting and recordkeeping hour burden

- | | |
|---------------------------|-------------------|
| a. Number of respondents | <u>20,088,262</u> |
| b. Total annual responses | 20,088,262 |

- 1. Percentage of these responses collected electronically 100%
- c. Total annual hours requested 9,021,953
- d. Current OMB inventory 0
- e. Difference 9,021,953
- f. Explanation of difference
 - 1. Program change New Collection
 - 2. Adjustment

12B. Estimated Annualized Burden Costs

Annual reporting and recordkeeping cost burden (*in thousands of dollars*)

- a. Total annualized capital/startup costs 0
- b. Total annual costs (O&M) \$371,704.464
- c. Total annualized cost requested \$371,704.464
- d. Current OMB inventory 0
- e. Difference \$371,704,464
- f. Explanation of difference
 - 1. Program change New Collection
 - 2. Adjustment

13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

There are no capital costs associated with this collection.

14. Annualized Cost to Federal Government

There are no incremental costs to the government for this collection.

15. Explanation for Program Changes or Adjustments

This is a new collection effort so there are no changes or adjustments.

16. Plans for Tabulation and Publication and Project Time Schedule

A final rule is anticipated to be submitted for publication within 60 to 90 days. This does not require any statistical or other analysis.

17. Exceptions to Certification for Paperwork Reduction Act Submissions

“There are no exceptions to the certification.”