

**Requests for OMB Review and Approval For
Office of the National Coordinator for Health Information
Technology
US Core Data for Interoperability New Data Element Submission
Form**

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**Supporting Statement for
Office of the National Coordinator for Health Information
Technology
US Core Data for Interoperability (USCDI) New Data Element
Submission Form**

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Office of the National Coordinator for Health Information Technology is seeking the approval for a new information collection request item the “US Core Data for Interoperability (USCDI) New Data Element Submission Form.”

The [U.S. Core Data for Interoperability \(USCDI\)](#) is a standardized set of health data classes and constituent data elements used to support nationwide, interoperable health information exchange. When published, the USCDI will become the required standard data elements set to which all health IT developers must conform to obtain ONC certification. The ONC certification is required for participation in some federal healthcare payment plans.

In order to insure the USCDI remains current and reflects the needs of the health IT community, ONC has established a predictable, transparent, and collaborative process to solicit broad stakeholder input to expand the USCDI. Anyone, including ONC staff, staff from other federal agencies, and other stakeholders may submit proposals for new data elements. These contributions will be in the form of public comments through our Health IT Advisory Committee (HITAC) as well as direct public contributions by proposing new data classes and data elements for addition to future versions of this health IT standard. The ONC will evaluate each submission in collaboration with the HITAC and upon approval by the National Coordinator for Health IT, new data classes and data elements from these submissions will be added to the newest version of the USCDI standard for integration into health information technology products such as electronic health records.

2. Purpose and Use of Information Collection

The information collected from this submission system will:

- (1) Comprise the sum total of the items ONC will evaluate for addition to the next version of the USCDI.
- (2) Provide supporting documentation to justify addition of the data elements to the USCDI or, if the documentation does not justify addition to the USCDI, to one of several levels of candidate data elements for future development and consideration.
- (3) Be publically available for review at any time to provide transparency and predictability in the USCDI expansion process.
- (4) Contain information about the submitter to allow direct feedback on ONC's decisions to add or not add a submission to a future version of the USCDI.

3. Use of Improved Information Technology and Burden Reduction

Submitters will use this web-based tool designed to be easy-to-use, self-explanatory and self-paced to alleviate burden on the submitters. It will:

- a) Provide simple instructions that provide instant feedback on the quality of the submission.
- b) Have error preventing features such as fixed drop down lists and "check all that apply" lists where appropriate.
- c) Have the ability to attach supporting documents rather than manually enter large blocks of text.
- d) Have the ability to save progress and to return to an incomplete submission or edit a completed submission.
- e) Have appropriate use of branch and skip logic where to minimize the need to complete irrelevant sections.

4. Efforts to Identify Duplication and Use of Similar Information

This is the first time this information has been collected, as the USCDI is a new construct and the process to submit data elements for addition to the USCDI is newly defined.

5. Impact on Small Businesses or Other Small Entities

This data collection system impacts all entities, including individuals and small businesses, equally. The information being requested or required has been held to the absolute minimum required for the intended use of the data.

6. Consequences of Collecting the Information Less Frequent Collection

This system will collect each submission only once, not on an ongoing basis. However, during ONC's evaluation process, supplemental information may be submitted if not available at the time of initial submission or if requested by ONC to properly conduct the evaluation.

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

This data collection request is fully consistent with the guidelines. There are no special circumstances required for the collection of information in this data collection.

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

A 60-day Federal Register Notice was published in the *Federal Register* on Tuesday, February 11, 2020, Vol. 85, No. 28, Page 7764. There were no comments received.

The Health Information Technology Advisory Committee (HITAC), ONC’s principal advisory body under Federal Advisory Committee Act (FACA), provided recommendations to ONC for the amount and details of information required for these submissions. Within this letter, Recommendation 9 addresses data elements that should be required. The HITAC is composed of members of several federal agencies including CDC for public health concerns.

9. Explanation of any Payment/Gift to Respondents

There will be no payments or gifts to submitters for their participation in the submission process. It is voluntary.

10. Assurance of Confidentiality Provided to Respondents

The submitter’s organization, but not the personal contact information, will be published as part of the submission. Submitters will be notified that the substance of a submission may reveal some or all of a submitter’s identity, even without the individual identifying characteristics like name, phone number or email address.

11. Justification for Sensitive Questions

No questions of a sensitive nature are asked in this data collection.

12. Estimates of Annualized Hour and Cost Burden

We estimate that a new submission with 1-5 individual data elements in a single data class will take 20 minutes to complete. Submissions with a larger number of data elements or in multiple data classes will take proportionately longer.

The survey was pre-tested with four separate respondents from which we derived the 20 minute burden per respondent burden estimate.

Exhibit 1. **Estimated Annualized Burden Hours**

Type of Respondent	Form Name	No. of Respondents	No. of Responses per	Average Burden per Response (in hours)	Total Burden
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			Respondent		Hours
HIT Stakeholder	USCDI Submission	100	1	20/60	33
Total					33

Exhibit 2. **Estimated Annualized Burden Costs**

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
HIT Stakeholder	33	\$100 ¹	\$3,300.00
Total			\$3,300.00

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

There are no annualized capital/startup or ongoing operation and maintenance costs involved in collecting the information.

14. Annualized Cost to Federal Government

The estimated cost to the Federal Government for the *USCDI New Data Element Submission System* data collection activities is \$150,000 over 2 years or \$75,000 annually, based on

- a. Cost of contract for development and maintenance of the web service that will support the submission system - \$15,000, based on 150 hours of contractor development and maintenance time.
- b. Annual cost of federal hours to manage this web service contract specific to this new data collection process - \$10,000 based on 100 hours at \$50 per hour.
- c. Annual cost of federal (ONC) hours providing research and analysis - \$50,000, based on an estimate of 1 hour of analysis per submission at \$50 per hour

15. Explanation for Program Changes or Adjustments

There are no program changes or adjustments as this is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The results of these submissions will be public, with the exception of any identifying information that is withheld per consent by the submitter, in tabular or similar form. Submissions may be archived following the completion of the annual process to evaluate

¹ Based on Computer and Information Systems Managers BLS employee category plus overhead and benefits (<https://www.bls.gov/ooh/management/computer-and-information-systems-managers.htm>)

the submissions, but will be available for retrieval and review. These tables will be used by ONC during the submission evaluation process. The results of this evaluation process will append these tables to keep information about all phases of the process in one location.

These submissions and ONC's subsequent evaluation will inform ONC's decision to include or exclude these submissions in future versions of USCDI. Therefore, the submissions will remain public. This submission and analysis cycle will occur no less frequently than annually and may occur much more frequently, with analysis and feedback occurring shortly after submission.

This submission, evaluation and decision making process is ongoing and is expected to continue indefinitely.

17. Reason(s) Display of OMB Expiration Date is Inappropriate All data collection materials will display the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions There are no exceptions to the certification.