Supporting Statement Part A
Administrative Simplification HIPAA Compliance Review
(CMS-10662; 0938-1390)

Background

The authority for administering and enforcing compliance with the Administrative Simplification non-privacy Health Insurance Portability and Accountability Act (HIPAA) rules has been delegated to the Centers for Medicare & Medicaid Services (CMS). (68 FR 60694 Part F, October 23, 2003).

45 CFR § 160.308(a) states, "The Secretary will conduct a compliance review to determine whether a covered entity is complying with the applicable administrative simplification provisions when a preliminary review of the facts indicates a possible violation due to willful neglect." Further, 45 CFR § 160.308(b) states, "The Secretary may conduct a compliance review to determine whether a covered entity or business associate is complying with the applicable administrative simplification provisions in any other circumstance." Reviews conducted under § 160.308(b) are conducted at the discretion of the Secretary.

45 CFR § 160.310 requires that a covered entity provide records and compliance reports to the Secretary in cooperation with a compliance review. 45 CFR § 160.310 provides that a covered entity must permit HHS, or its delegated entity, access during normal business hours to its facilities, books, records, and other information, and other information necessary to determine compliance, but also provides that if the Secretary determines that "exigent circumstances exist, such as when documents may be hidden or destroyed," the covered entity must permit access at any time without notice.

The purpose of this collection is to retrieve information necessary to conduct a compliance review and carry out the authority delegated to CMS as described in CMS0014-N (68 FR 60694). These forms will be submitted to the Centers for Medicare & Medicaid Services (CMS), National Standards Group, from entities covered by HIPAA Administrative Simplification regulations. This collection is not applicable to HIPAA Privacy and Security Rules.

Although 45 CFR Part 160 outlined the authority to conduct compliance reviews, we did not have the resources to do so until recent years. A pilot was conducted in 2019 prior to implementation of a regular compliance review program. Since 2020, a contractor has been supporting regular, ongoing compliance reviews. A PRA was approved to support this work in 2024. We're looking to expand the impact of our compliance review program by increasing the number of covered entities subject to a review.

CMS is requesting a Revision approval from OMB due to changes made to the Compliance Review program between the last PRA request and this renewal request. In the last PRA request, we were auditing up to 50 entities and we are looking to expand the program to up to 100 entities annually. The program also made the following updates to communications sent to covered entities since the last PRA request; however, there are no changes to data/information collection requests:

- The single Covered Entity Triage Questionnaire submitted in the previous PRA request was duplicated so that there is a unique questionnaire for each covered entity type (Health Plan, Clearinghouse, Provider).
- All Operating Rule Attestation questions are now enumerated for ease of reference, and the hyperlink to each operating rule within the document are

updated to reflect the updated location on the CAQH CORE website.

- The signatory for all notices and letters was updated to reflect a change in National Standards Group (NSG) personnel and the change from the Office of Burden Reduction and Health Informatics (OBRHI) to the Office of Healthcare Experience and Interoperability (OHEI).
- The CMS logo for OBRHI within each document was updated to reflect the recent change to OHEI.
- The PRA disclosure statement located in the footer of each document was updated to include additional information related to PRA standards and the compliance review program.
- The PRA expiration date in the header of each document was updated to reflect the expiration extension until 12/31/2025.
- There are nine outdated documents that are now retired and will not be used by the Compliance Review program in the future (See Exhibit A Crosswalk).
- There are nine new documents to be used by the Compliance Review Program (See Exhibit A Crosswalk).

Justification

1. Need and Legal Basis

Section 1173 of the Social Security Act (the Act), 42 U.S.C. 1320d–2, and section 264 of HIPAA require the Secretary to adopt a number of national standards to facilitate the exchange of certain health information and to protect the privacy and security of such information.

The Secretary promulgated rules that relate to compliance with, and enforcement of, the HIPAA rules, which are codified at 45 CFR part 160, subparts C, D, and E and collectively referred to as the Enforcement Rule. The Secretary first issued an interim final rule promulgating the procedural requirements for imposition of civil money penalties on violations of the privacy standards on April 17, 2003, Civil Money Penalties: Procedures for Investigations, Imposition of Penalties (68 FR 18896). The Secretary subsequently proposed a rule on April 18, 2005, HIPAA Administrative Simplification: Enforcement; Proposed Rule (70 FR 20224), proposing the amendment of 45 CFR part 160, subparts A (General Provisions), C (Compliance and Enforcement), and E (Procedures for Hearing), and proposing a new subpart D (Imposition of Civil Money Penalties) that addressed the substantive issues related to the imposition of civil money penalties and proposing the above provisions be applied to all HIPAA rules.

2. Information Users

CMS enforcement staff would use the information provided by covered entities to assess HIPAA Administrative Simplification compliance regarding adopted transaction standards, code sets, unique identifiers, and operating rules. The information provided by covered entities consists of entity transaction files that are tested with an Edifecs transaction testing tools called Onboarding and Testing Cloud Services (OTCS) and Transaction Management (TM). If violations are reported by the testing tools, entities are notified and assisted with developing and completing a corrective action plan. Once corrective action is completed, entities' transaction files are retested for compliance.

3. Use of Information Technology

This process involves the use of electronic and paper collection techniques. It is expected that approximately 95% of the compliance review documents will be forwarded by the entity

electronically to the Centers for Medicare & Medicaid Services (CMS) Compliance Review Testing Tool (ASETT). The flow of information electronically allows for a more efficient process.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

This collection would impact covered entities that transmit transactions electronically. The burden is minimized by allowing any covered entity of any size to transmit to CMS these documents electronically.

6. Less Frequent Collection

This mandatory information collection will be conducted annually with up to 100 entities. We do not anticipate collecting the information less frequently, that is, less than one time per year with the selected covered entities, and still being able to meet our program requirements. We also do not foresee any reduction in the frequency, or the amount of information collected from each covered entity; however, as the Compliance Review Program matures there may be an opportunity to revise our program SOP. There are no known legal obstacles. Our goal is to reduce burden to the extent possible and remain compliant with program requirements. Our overarching goal is to foster industry compliance with HIPAA Administrative Simplification requirements. In furtherance of this goal, we're looking to increase the number of reviews we're able to conduct annually.

The more compliance reviews that we are able to conduct, the greater impact our program will have on advancing our authority to ensure widespread compliance across all covered entities. We do this with our compliance reviews that test transaction files for noncompliance. Our Compliance Review Program assists entities with achieving compliance, thereby reducing burden, and increasing industry benefits from administrative simplification.

7. Special Circumstances

Explain any special circumstances that would cause an information collection to be conducted in a manner:

- requiring respondents to report information to the agency more often than quarterly;
- requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- requiring respondents to submit more than an original and two copies of any document;
- requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- requiring the use of a statistical data classification that has not been reviewed and

approved by OMB;

- that includes a pledge of confidentiality that is not supported by authority established in statue or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

- requiring respondents to submit proprietary, trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

This information collection does not contain any special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on 1/14/2025 (90 FR 3220).

One comment was received during the 60-day comment period regarding this PRA package and CMS responded to said comment within a separate response to comment document. No changes were made as a result of CMS response.

The 30-day Federal Register notice published on 6/11/2025 (90 FR 24632).

9. Payments/Gifts to Respondents

There will be no payments and/or gifts to respondents. Non-responsiveness to a compliance review notification could result in further investigation and assessed money penalties.

10. Confidentiality

Without the information requested, CMS may be unable to proceed with the compliance review process. CMS collects this information under authority of CMS0014- N (68 FR 60694) issued pursuant to the HIPAA. CMS will use the information provided to conduct HIPAA Administrative Simplification Non-Privacy/Security compliance reviews. Information submitted on these forms is treated confidentially and is protected under the provisions of the Privacy Act of 1974. Names or other identifying information about individuals are disclosed only when it is necessary for investigation of possible HIPAA A.S. Non- Privacy/Security violations, for internal systems operations, or for routine uses, which include disclosure of information outside the Department for purposes associated with HIPAA A.S. Non-Privacy/Security compliance and as permitted by SORN 09-90-0052.

11. Sensitive Questions

This information collection does not contain any sensitive questions.

12. Burden Estimates (Cost and Time)

The covered entity reporting burden for collection of information on the above-note forms is estimated to average 150 minutes (or 2.5 hours) per form and there are 4 forms. The initial forms are assumed to be assigned to a general analyst within the covered entity organization. An entity will only be required to participate in one compliance review per year.

The calculations below for cost and time are based on the 2023 Department of Labor, Bureau of Labor Statistics estimation for the median hourly labor wage of a General Healthcare Worker (https://www.bls.gov/oes/current/oes319099.htm). We added 100% of the median hourly labor wage to the value to account for fringe and overhead (which would include the time for reviewing instructions, gathering the data needed, and entering and reviewing the information on the completed form), which brings the total hourly wage to $21.39 + 21.39 = $42.78.

Table 1 - Burden per General Healthcare Worker at $42.78 per Covered Entity

Document	Time Performed (hours)	Total
Triage Questionnaire	2	$85.56
Operating Rule Attestation	2.5	$106.95
Entity Information (Part B)	0.5	$21.39
Artifact Information (Part C)	5	$213.90
TOTAL	**10**	**$427.80**

Table 2 - Total Annual Time Burden

Number of Entities per Year	Response per Entity	Hours per Response	Maximum Annual Time Burden (hours)
Up to 100	1	10	**1,000**

Table 3 - Annual Cost per General Healthcare Worker Response per Entity

Number of Artifacts per Entity	Time (Hours)	Analyst Wage	Total Analyst Wage per Entity
4	10	$42.78	**$1,711.20**

Table 4 - Total Annual General Healthcare Worker

Number of Participating Entities	Total Analyst Wage per Entity	Maximum Annual Cost
Up to 100	$1,711.20	**$171,120.00**

It is estimated that 80% of the covered entities assessed are subject to be placed on a Corrective Action Plan (CAP). To correct the entities' deficiencies, the Compliance Officer may be asked to provide the following:

a. Structured CAP
b. Written Follow-Up with Explanation of Deficiencies

Time, labor, and correspondence may incur an additional cost as indicated below. Labor costs are based on the completion/review by each entity's Compliance Officer. We used the mean hourly 2023 Department of Labor rate of $38.55 reported for a Compliance Officer from the Department of Labor, Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes131041.htm) at $38.55/hour at 11 hours per correction, which comprises administrative burden, hourly wage, overhead, and incidentals of structuring and monitoring the CAP. We added 100% of the mean hourly wage, which brings the total hourly wage to $38.55 + 38.55 = $77.10. A Compliance Officer role is used because they have

approval authority.

Table 5 - Collective Structuring and Monitoring CAP Cost per Entity

CAP Activity	Entity Placed on CAP	Time (hours)	Hourly Wage	Collective CAP Cost
Structuring	1	11	$77.10	**$848.10**
Monitoring	1	40	$77.10	**$3,084.00**
			TOTAL	**$3,932.10**

Table 6 - Annual Structuring and Monitoring CAP Cost for All Entities

CAP Activity	Number of Entities Placed on CAP	Time (hours)	Hourly Wage	Maximum Collective CAP Cost
Structuring	40	11	$77.10	**$33,924.00**
Monitoring	40	40	$77.10	**$123,360.00**
	TOTAL	**2,040**		**$157,284.00**

Table 7 - Total Administrative Impact to Industry

Maximum Annual Collective General Healthcare Worker Cost	Maximum Annual Collective Compliance Officer Cost	Maximum Industry Impact
$85,560.00	$**157,284.00**	**$242,844.00**

13. Capital Costs

There are no capital costs for this collection.

14. Cost to Federal Government

Table 8- Total Cost Federal Analyst

Time (Hours)	Analyst Annual Wage
2080 (1 FTE)	**$117,962 (GS13 Step 1)**

Table 9- Total Cost Federal Contractor

Number of Entities under Compliance Review	Time (hours)	Hourly Analyst II Wage	Maximum Contractor Cost
Up to 100	30	$107.47	**$3,224.10**

15. Changes to Burden

This is a revision information collection request. The following document changes were made since the last PRA; however, there are no changes to data/information collection requests:

- The single Covered Entity Triage Questionnaire submitted in the previous PRA request was duplicated so that there is a unique questionnaire for each covered entity type (Health Plan, Clearinghouse, Provider).
- All Operating Rule Attestation questions are now enumerated for ease of reference, and the hyperlink to each operating rule within the document are updated to reflect the updated location on the CAQH CORE website.
- The signatory for all notices and letters was updated to reflect a change in National Standards Group (NSG) personnel and the change from the Office of Burden Reduction and Health Informatics (OBRHI) to the Office of Healthcare Experience and Interoperability (OHEI).
- The CMS logo for OBRHI within each document was updated to reflect the recent change to OHEI.
- The PRA disclosure statement located in the footer of each document was updated to include additional information related to PRA standards and the compliance review program.
- The PRA expiration date in the header of each document was updated to reflect the expiration extension until 12/31/2025.
- There are nine documents that were outdated and are now retired and will not be used by the Compliance Review program in the future (See Exhibit A Crosswalk).
- There are nine new documents to be used by the Compliance Review Program (See Exhibit A Crosswalk)

Additionally, NSG is looking to increase the number of reviews we're able to conduct annually- up to 100 annually. The more compliance reviews that we're able to conduct, the greater impact our program will have on advancing our authority to ensure widespread compliance across all covered entities.

16. Publication/Tabulation Dates

CMS does not plan to publicly disclose any of the information collected.

17. Expiration Date

CMS will display the expiration date on each collection instrument. It is displayed in the PRA Disclosure Statement as well as in the header and footer of each document.

18. Certification Statement

There are no exceptions to the certification statement.