

**Supporting Statement for Indian Health Service
Forms to Implement the Privacy Rule (OMB No. 0917-0030)
(45 C.F.R Parts 160 & 164)**

Background

This is a request for an extension of the previously approved information collection, Indian Health Service (IHS) Forms to Implement the Privacy Rule (OMB No. 0917-0030) (45 C.F.R. Parts 160 & 164).

A. Justification

1. Circumstances Making the Collection of Information Necessary:

This is a request for an extension of a previously approved collection with no changes.

This collection of information is made necessary by the Department of Health and Human Services' rule entitled "Standards for Privacy of Individually Identifiable Health Information" (Privacy Rule) (45 C.F.R. Parts 160 and 164). The Privacy Rule implements the privacy requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, creates national standards that protect patient health information, and allows our patients access to their health information. Title Privacy Rule, 45 C.F.R. §§ 164.508, 164.522, 164.526 and

164.528, requires the collection of information to implement these protection standards and access requirements.

Under the Privacy Rule, IHS is considered a covered entity and is subject to the Rule. Therefore, IHS has developed and implemented methods to meet the information collection requirements.

2. Purpose and Use of the Information Collection:

The following (A. 2) provides a description of the data collection forms IHS currently uses to implement the Rule.

(a) 45 C.F.R. § 164.508 - Authorization for Use or Disclosure of Protected Health Information (IHS-810)

45 C.F.R. § 164.508 requires covered entities to obtain or receive a valid authorization for its use or disclosure of protected health information for other than treatment, payment and healthcare operations. Under this provision, individuals may initiate a written authorization permitting covered entities to release their protected health information to entities of their choosing. The form IHS-810 “Authorization for Use or Disclosure of Protected Health Information” is used by patients at IHS facilities to document and authorize the use, disclosure or release of their protected health information from their medical record to anyone they specify.

(b) 45 C.F.R. § 164.522(a)(1) - Request For Restriction(s) (IHS-912-1)

Under the Privacy Rule, an individual can request to restrict the use of his or her information with some exceptions. Section 164.522(a)(1) requires a covered entity to permit individuals to request that the covered entity restrict the use and disclosure of their protected health information. The covered entity may or may not agree to the restriction. The form IHS-912-1 “Request for Restrictions(s)” is used to document an individual’s request for restriction of their protected health information and whether IHS agreed or disagreed with the restriction.

(c) 45 C.F.R. §164.522(a)(2) - Request For Revocation of Restriction(s) (IHS- 912-2)

Section 164.522(a)(2) permits a covered entity to terminate its agreement to a restriction if the individual agrees to or requests the termination in writing. The form IHS-912-2 “Request for Revocation of Restriction(s)” is used to document the agency or individual request to terminate a formerly agreed to restriction regarding the use and disclosure of protected health information. A previous request to restrict information may be revoked by the individual or IHS.

(d) 45 C.F.R. § 164.528 and 45 C.F.R. § 5b.9(c) - Request for an Accounting of Disclosures (IHS-913)

These provisions require covered entities to permit individuals to request that the covered entity provide an accounting of disclosures of protected health information made by the covered entity. The form IHS-913 “Request for an Accounting of Disclosures” is used for the collection of information for the purpose of processing, an accounting of disclosures at the request of the patient and/or personal representative, and to document that request.

(e) 45 C.F.R. § 164.526 - Request for Correction/Amendment of Protected Health Information (IHS-917)

This provision requires covered entities to permit an individual to request that the covered entity amend protected health information. If the covered entity accepts the requested amendment, in whole or in part, the covered entity must inform the individual that the request for an amendment is accepted. If the covered entity denies the requested amendment, in whole or in part, the covered entity must provide the individual with a written denial. The IHS developed the form (IHS 917) to permit individuals to submit their request and to document IHS’s acceptance or denial of a patient’s request to correct or amend their protected health information.

3. Use of Improved Technology and Burden Reduction:

IHS has made these forms available for staff, patients, and others via the internet in PDF format, and they are fillable, as well. These forms are available online at the following Website addresses: <http://www.ihs.gov/CIO/PUF> and <http://www.hhs.gov/forms/publicuse.html>. Currently, IHS is only authorized to use facsimile and the secured mail to receive/submit completed forms which contain PHI. In the future, the forms may be made available for online completion and submission, as IHS' increases its ability to adequately safeguard electronic PHI and offer patient electronic signatures, (i.e., encryption, secure website, etc.).

4. Efforts to Identify Duplication and Use of Similar Information:

Similar health data collection information may be collected by the public and/or private sector entities in response to implementation of the Privacy Rule. However, the data collection instruments being submitted for approval are for IHS health programs.

5. Impact on Small Businesses or Other Small Entities:

This collection of information will not impact small business or other small entities. The information being requested or required has been held to the absolute minimum required for the intended use.

6. Consequences of Collecting the Information Less Frequently:

If the collection is not conducted or is conducted less frequently, IHS would be unable to properly implement the data collection requirements contained in the Privacy Rule. This on-going collection of information is only collected when respondents choose to complete and submit data collection instruments. There are no technical or legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines within 5 C.F.R. § 1320.5:

There may be special circumstances, such as HHS Office for Civil Rights requesting documentation during a HIPAA Privacy investigation, that require exceptions to 5 C.F.R. § 1320.5(d)(2).

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

In accordance with 5 C.F.R. 1320.8(d), a 60-day notice to solicit public comment was published in the *Federal Register* (84 Fed. Reg.19088) on (May 3, 2019). One comment was received, but it did not pertain to the collection itself. Also, a 30-day notice for public comment was published in the *Federal Register* (84 Fed. Reg.42935) on (August 19, 2019) to allow for public comment to be submitted directly to OMB, as required by 5 C.F.R. § 1320.10(a).

9. Explanation of any Payment/Gifts to Respondents:

The respondents did not receive any payment or gifts for providing the information.

10. Assurance of Confidentiality Provided to Respondents:

The information collected is subject to the Privacy Act of 1974 and the HIPAA regulations and will be collected and maintained in accordance with IHS Privacy Act system notice 09-17-0001, IHS Medical, Health and Billing Records. The information collected will be kept private to the extent allowed by law.

11. Justification for Sensitive Questions:

There are no questions of a sensitive nature solicited in this information collection.

12. Estimates of Annualized Burden Hours (Total Hours & Wages):

A. The table below provides estimated annual burden hour for this collection.

Table - Estimated Annual Burden Hours				
Data Collection Instruments	Estimated Number of Respondents	Responses per Respondent	Average Burden Hour per Response*	Total Annual Burden Hours
“Authorization for Use or Disclosure of Protected Health Information” (OMB No. 0917-0030, IHS-810)	210,954	1	10/60	35,159
“Request for Restriction(s)” (OMB No. 0917-0030, IHS-912-1)	214	1	10/60	36

“Request for Revocation of Restriction(s)” (OMB No. 0917-0030, IHS-912-2)	3	1	10/60	.5
“Request for Accounting of Disclosures”(OMB No. 0917-0030, IHS-913)	39	1	10/60	6.5
“Request for Correction/Amendment of Protected Health Information” (OMB No. 0917-0030, IHS-917)	54	1	10/60	9
Total Annual Burden	211,264			35,211.5

*For ease of understanding, burden hours are provided in actual minutes.

The total estimated burden for this collection of information is 35,212 hours.

B. The table below provides estimated annual costs to respondents for this collection.

Instrument	Total Burden Hours	Hourly Wage Rate	Respondent Cost
Form 810	35,159	\$17.00	\$ 597,703.00
Form IHS-912-1	36	\$17.00	\$ 612.00
Form IHS-912-2	.5	\$17.00	\$ 8.50
Form 913	6.5	\$17.00	\$ 110.50
Form 917	9	\$17.00	\$ 153.00
Total Respondent Cost			\$ 598,587.00

This information collection places no additional computer or record keeping requirements upon the respondents. Therefore, the estimated total annual cost burden to respondents or record keepers for capital and start-up costs components (annualized over the expected useful life) for this information is zero.

The information collection will not require the purchase of any capital equipment nor

create any start up costs. This process allows respondents to choose the type of collection, voluntarily. These information collections are part of the respondents' customary and usual business practices, and, therefore is not included in the estimate.

13. Estimates of other Total Annual Cost Burden to Respondents or Record-keepers/Capital Costs:

There are no direct costs to respondents other than the time it takes to voluntarily provide the information for consideration.

There are no capital or start-up costs to respondents for this information collection. Nor are there costs for the operation and maintenance, and purchase of services components for this information collection.

14. Annualized Cost to Federal Government:

The annual cost to the Federal Government for this information collection is the cost of maintaining capital associated with this information collection which is based on (1) the annual equipment, overhead, and printing expenses; and (2) the staff time to perform the services required for the Information Collection (i.e., the actual data collection, processing of forms, and any other administrative process). The estimated annual cost to the government for the information collection is \$1,260,000.

<u>ITEM</u>	<u>COST</u>
Healthcare Professional/Staff 200 staff x \$30/hr. x 2 hrs. x 5 days x 12 months)	\$ 720,000
Other expenses: equipment, overhead, and printing	\$ 300,000
Estimated total annual capital cost	\$1,020,000

15. Explanation for Program Changes or Adjustments:

There are no program changes or adjustments. There was a change in IHS-810 Form to include an option for the respondents to release information to Health Information Exchanges. This change is due to the technology solution to share patient information electronically in order to meet Meaningful Use Stage 2 with the IHS’s certified electronic health record, as required by 42 C.F.R. Parts 412, 413, and 495.

The program also made a change in the burden estimate; decreasing the burden hours on two forms, the IHS-810 and IHS-917, from 20 minutes to 10 minutes to more accurately reflect the actual time it takes to complete the form(s). Additionally, the number of respondents were decreased for all five forms to reflect actual baseline numbers collected and provided by the Area HIMs. Also, in the table under 12B., “estimated annual costs to respondents for this collection,” the hourly wage rate for respondents was changed from \$19 per hour to \$17 per hour to more accurately reflect the actual wages of American Indians and Alaska Natives (AIAN). The average annual income of American

Indians was \$36,252 and the poverty rate was 29%, in 2014 (United States Census Bureau, 2015) (See US Census webpage, “Facts for Features: American Indian and Alaska Native Heritage Month: November 2014” at <http://www.census.gov/newsroom/facts-for-features/2014/cb14-ff26.html>). Further, the average annual income for AIANs may even be lower as the United States Bureau of Labor Statistics (BLS) reported a 54% population-employment ratio for AIANs, with an 11.3% average unemployment rate. (See BLS report “Labor Force Statistics by Race and Ethnicity, 2014” at <http://www.bls.gov/opub/reports/cps/labor-force-characteristics-by-race-and-ethnicity-2014.pdf>).

16. Plans for Tabulation and Publication and Project Time Schedule:

There is no intention to publish this information collection.

17. Reason(s) Display of OMB Expiration Data is Inappropriate:

The OMB expiration date will be displayed on the data collection instruments.

18. Exceptions to Certification for Paperwork Reduction Act Submission:

There are no exceptions to the certification.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection.