

Supporting Statement

IHS HIPAA FORMS

A. JUSTIFICATION

1. Circumstances making the collection necessary:

This is a request for an extension on a previous approved collection. 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 CFR Parts 160 and 164). The Privacy Rule implements the privacy requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 and creates national standards to protect individuals’ personal health information and gives patients increased access to their medical records. Sections, 45 CFR 164.508, 522, 526 and 528 of the Privacy Rule require the collection of information to implement these protection standards and access requirements (Attachment 1).

Considered a covered entity under the Privacy Rule, the Indian Health Service (IHS) is subject to the Rule and must develop and implement methods to meet the information collection requirements contained in the rule. A.2 below describes the data collection forms and/or formats IHS proposes to use to implement the Rule.

2. **Purpose and use of the information collection:**

45 CFR 164.508 Authorization for Use or Disclosure of Health Information (IHS-810)

This form is currently used by the Indian Health Service facilities but is being updated to comply with the new Privacy Rule and IHS program changes. The update takes into consideration the special requirements for use or disclosure of Psychotherapy notes and other sensitive medical information. This form will be used for authorizing IHS health programs to release health information to other health facilities for continuing care, and for authorizing IHS health programs to use information for other lawful purposes other than for health care by any member of the public that has ever received IHS health services. The form will also be used to send or transfer information to anyone specified by an individual who has received IHS health services.

We administratively made changes to reflect the understanding of the language to our patients in regards to the revocation statement in Section V as well as making the instruction on the back of the form more clearer for our staff. The original area for individual designation of an optional expiration date was said to be confusing by most staff. Other than making the expiration date more understandable, the intent of the form remains the same.

45 CFR 164.522 (a)(1) - Request For Restriction (s)(IHS 912-1)

The provision in this section requires the collection of information at the request of an individual for the purpose of restricting access to their information. Under the Privacy Rule, an individual can restrict the use of his or her information with some exceptions. The form IHS-912-1 will be used for documenting such restriction. An administrative change to the Signature Box for the Personal Representative needed clarification.

45 CFR 164.522 (a)(2) – Terminating a Restriction (IHS 912-2)

A previous request to restrict information can sometimes be revoked at the option of an individual. The form IHS-912-2 will be used to document such revocation. An administrative change to the Signature Box for the Personal Representative needed clarification.

45 CFR 164.526 Request for Correction/Amendment of Protected Health Information (IHS 917)

The provisions of this section require the collection of this information for the purpose of correcting or amending previously documented information. The form can also be used as a means of communicating denial or acceptance of such requests. Although correcting or amending a medical record has always been one of the benefits under the Privacy Act, it has never been widely known and reported. With the focus of HIPAA Privacy Rule and its wide publicity, we expect that more people will now request that their records be corrected and or amended.

We have administratively re-numbered this form to IHS 917 due to the concerns expressed by IHS staff about the September 11, 2001 (9/11) terrorist attacks. It was the unanimous consensus of the reviewing staff that numbering a form 911 is an unintended reminder of the event. The renumbering has not in any way affected its intended uses. An administrative minor changes per instructions from the HHS/Office of Civil Rights (OCR). IHS has make an additional administrative change to the Signature Box for the Personal Representative needed clarification.

45 CFR 164.528 – Request For An Accounting of Disclosures (IHS 913)

The provisions in this section require the collection of information for the purpose of processing an accounting of disclosures at the request of a beneficiary. While this has also been a provision under the Privacy Act, it was not widely known by the public. The recent publicity concerning patient rights under HIPAA Privacy Rule has made the public more aware of this provision. This has resulted in an increase requests for an accounting of their record disclosures. IHS has make an additional administrative change to the Signature Box for the Personal Representative needed clarification.

3. Use of information technology to reduce the burden of the collection on the public:

IHS has made these forms available online for staff use at IHS facilities in PDF format and fillable as well as made them available for our patients and others via internet access. The forms may also be made available online at the IHS website (www.ihs.gov) and at the DHHS Program Support Center (PSC) website at (<http://Forms.PSC.GOV>) where they can be

downloaded by members of the public. In the future the forms may be made available for online completion and submission, however this will have to wait until adequate technology and safeguards are in place. There are no known barriers for the use of electronic technology to collect the information and reduce the burden of this collection.

4. Efforts to identify duplication and use of similar information:

Similar health data collection information may be collected by other public and or private sector entities in response to implementation of the Privacy Rule, however, the data collection instruments being requested for approval are for IHS health programs use only and will not be duplicated by other entities.

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, the IHS would be unable to properly implement the data collection requirements contained in the Privacy Rule. This ongoing 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 burden.

7. Special circumstances relating to the guidelines at 5 CFR 1320.5(d) (2):

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

8. Efforts to consult with the public and a representative sample of respondents:

The Agency's 60-day notice soliciting comments on the information collection prior to submission to OMB required by 5 CFR 1320.8(d) was published in the Federal Register on November 5, 2002 (Pages 67411-67412).

Efforts to consult persons outside the agency:

The forms were electronically distributed to all the components of the Department of Defense (DOD), Department of Veteran Affairs (VA), Bureau of Prisons of the U.S. Department of Justice (DOJ), the U.S. State Department, and all members of the Federal Inter-Agency Committee on Medical Record for their review and comments. We did not receive any suggested changes from these Agencies. They were generally satisfied with the forms as reflected in a face to face meeting with some of the members on November 5, 2002.

Consultation with representatives of those from whom information is to be obtained or those who must compile records:

The data collection instruments were field tested at the Fort Duchesne IHS Health Center, Fort Duchesne, Utah to determine whether data collection instruments and instructions were clear and user friendly. Changes and revisions were made to the data collection instruments as a result of this consultation.

There are no unresolved issues regarding this collection of information.

9. Explanation of payment or gifts to respondents:

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

10. Assurance of confidentiality provided to respondents:

There is no assurance of confidentiality provided to respondents concerning this information collection. Identifiable information will be collected and maintained in accordance with IHS Privacy Act system notice 09-17-0001, “ IHS Medical, Health and Billing Records”. IHS contractors will be required to collect and maintain identifiable information in accordance with the Privacy Act of 1975, IHS system notice 09-17-0001, HIPAA regulations and as stated in the contract.

11. Justification for sensitive questions:

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

12. Estimate of the reporting and record keeping “hour” burden:

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

Table - Estimated Annual Burden Hours				
45 CFR Sections	No. of Respondents	Responses per Respondent	Burden per Response*	Total Annual Burden
164.508 IHS Form 810	500,000	1	20 mins	166667
164.522(a)(1) Form IHS-912-1	15000	1	10 mins	2500

164.522(a)(2) Form IHS-912-2	5000	1	10 mins	833
164.526 IHS Form 917	7500	1	15 mins	1875
164.528 IHS Form 913	15000	1	10 mins	2500
Total Annual Burden	542,500	5	65 mins	17437 5

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

The total estimated burden for this collection of information is 174,375 hours.

13. Estimate of the reporting and record keeping “cost” burden to respondents:

There are no direct costs to respondents other than the time it takes to voluntarily provide the information for consideration. The estimated cost in time to respondents, as a group, is \$2,092,500 (174375 burden hours (times) an average hourly rate of \$15.00).

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. Estimate of the annualized cost to the Federal Government:

The estimated annual cost to the government for the information collection is \$4,160,000.00. This was based on:

- A) Professional and support staff time to explain the reasons for the information Collection, development of the data collection and actual assistance in making the collection, and other administrative process (200 employees working 2 hours per each day at \$40.00 per employee).
- B) Other expenses: equipment, overhead, printing: \$300,000.00.

15. Program changes or adjustments requested as noted in #13 of 83-I:

This is a new collection of information.

16. Publishing the results of the information collection:

There is no intention to publish this information collection.

17. Approval not to display the expiration date:

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

18. Request exceptions to the certification statement in item 19 of Form OMB 83-I:

IHS is not seeking any exceptions.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection.