Supporting Statement for Indian Health Service Health Insurance Portability and Accountability Act Forms and Supporting Regulations Contained in 45 CFR Parts 160 and 164

Background
Revision of the Indian Health Service (IHS) Health Insurance Portability and Accountability Act (HIPAA) FORMS

A. Justification

1. Circumstances Making the Collection of Information Necessary:

This is a request for a revision on a previously approved collection due to changes to the instructions on the form other than that no changes were made to burden hours. 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@(APrivacy 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 that protect patient health information and gives our patients access to their health information. 45 CFR Sections 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, IHS is subject to the Rule and has developed and implemented methods to meet the information collection requirements. A.2 below describes the data collection forms IHS proposes to use to implement the Rule.

2. Purpose and Use of the Information Collection:

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

This form is currently used by the IHS facilities and was updated to comply with the 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 by the patient for authorizing IHS health programs to release

health information from their record to anyone they specify.

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 unambiguous 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.

(b) 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(s). An administrative change to the Signature Box for the Personal Representative and Witness needed clarification.

(c) 45 CFR 164.522(a) (2) B Request For Revocation of Restriction(s) (IHS 912-2)

A previous request to restrict information may be revoked by the individual or IHS. The form IHS-912-2 will be used to document such revocation. An administrative change to the Signature Box for the Personal Representative and Witness needed clarification.

(d) 45 CFR 164.528 and 45 CFR 5b.9(c) B 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 the patient and/or personal representative. An administrative change to the Signature Box for the Personal Representative and Witness needed clarification.

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

The provisions of this section required IHS to develop this

form to accept or deny a patient's request to correct or amend their protected health information. An administrative change to the Signature Box for the Personal Representative and Witness needed clarification.

3. Use of Improved Technology and Burden Reduction:

IHS has made these forms available online for our staff in PDF format and fillable as well as made them available for our patients and others via internet access. These forms are available online at: http://www.ihs.gov/CIO/PUF and USA.gov http://www.forms.gov/bgfPortal/main.do. Currently, IHS is only authorized to use facsimile and the mail to receive/submit completed forms which contain PHI. In the future the forms may be made available for online completion and submission; however this will be dependent on IHS ability to adequately safeguard electronic PHI, 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 requested 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 Frequent Collection:

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 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 burden.

7. Special Circumstances Relating to the Guidelines at 5 CFR 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 CFR 1320.5(d)(2).

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

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 June 24, 2009 (Page 30095, Vol. 74). There were no public comments received in response to this notice.

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 Records 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.

There are no unresolved issues regarding this collection of information.

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 collected and maintained in accordance with IHS Privacy Act system notice 09-17-0001, AIHS Medical, Health and Billing Records@ and 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

45 CFR Sections	Number of Respondents	Responses per Respondent	Burden per Responses*	Total Annual Burden
164.508 IHS Form 810	500,000	1	20 mins	166667
164.522(a)(1) Form IHS-912-1	15,000	1	10 mins	2500
164.522(a)(2) Form IHS-912-2	5,000	1	10 mins	833
164.528 IHS Form 913	15,000	1	10 mins	2500
164.526 IHS Form 917	7,500	1	15 mins	1875
Total Annual Burden	542,500	1	65 mins	174375

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

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

Instrument	Total Burden Hours	Hourly Wage Rate	Respondent Cost
Form 810	166667	$19.00	$3,166,673
Form IHS-912-1	2500	$19.00	$ 47,500

Form IHS-912-2	833	$19.00	$ 15,827
Form 913	2500	$19.00	$ 47,500
Form 917	1875	$19.00	$ 35,625
		Total Respondent Cost	$3,313,125

The total estimated burden for this collection of information is 587,708 hours.

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. Once available in electronic format, this process will allow respondents to choose this type of collection. 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 Recordkeepers/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 is based on the annual equipment, overhead, and printing expenses; and, the staff time to perform the services required for the Information Collection, development of the data collected and actual assistance needed in making the collection and any other administrative process. The estimated annual cost to the government for the information collection is $1,260,000.

ITEM COST

Healthcare Professional/ Staff 200 staff x $40/hr X 2 hrs x 5 days x 12 months)	$ 960,000
Other expenses: equipment, overhead, and printing	$ 300,000
Estimated annual capital cost	$1,260,000

15. Explanation for Program Changes or Adjustments:

This is an adjustment due to miscalculation in the burden and respondents in the previous collection.

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.