SUPPORTING STATEMENT FOR REQUEST FOR AND AUTHORIZATION TO RELEASE MEDICAL RECORDS OR HEALTH INFORMATION

<u>VA Form 10-5345</u>, Request For and Authorization to Release Medical Records or Health Information <u>VA Form 10-5345a</u> - Individuals' Request For a Copy of Their Own Health Information <u>VA Form 10-5345a-MHV</u> (My HealtheVet) Individuals' Request For A Copy of Their Own Health Information

OMB 2900-0260

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary. Identify legal or administrative requirements that necessitate the collection of information.

Section 7332, Title 38, United States Code, requires VA to obtain prior written consent from a patient before information concerning treatment for alcoholism or alcohol abuse, drug abuse, sickle cell anemia, or infection with the human immunodeficiency virus (HIV) can be disclosed from a patient medical record. This special consent must indicate the name of the facility permitted to make the disclosure, the name of the individual or organization to whom the information is being released, specify the particular records or information to be released, be under the signature of the Veteran and dated. It must also reflect the purpose for which the information is to be used, include a statement that the consent is subject to revocation and the date, event or condition upon which the consent will expire if not revoked before. Written patient consent is also required by the Privacy Act of 1974, VA confidentiality statute 38 U.S.C. 5701, and the Standards for Privacy of Individually Identifiable Health Information, hence HIPAA Privacy Rule, 45 Code of Federal Regulations Parts 160 and 164. VA Form 10-5345 is used for this purpose.

VA Form 10-5345a, Individuals' Request for a Copy of their Health Information, is used when the individual is making their own request. Individuals have a right to a copy of their health information maintained in agency records pursuant to the Privacy Act and HIPAA Privacy Rule. Per VA regulation 38 CFR §1.577 the requirements for such a request must be in writing, contain a reasonable description of the records and be over the signature of the requestor.

VA requests to add a third form to the current information collection. VA Form 10-5345a-MHV (My HealtheVet), Individuals' Request for a Copy of their Health Information is used when the individual is making a request for their information electronically via My HealtheVet. Individuals have a right to a copy of their health information maintained in agency records pursuant to the Privacy Act and HIPAA Privacy Rule. Per VA regulation 38 CFR \$1.577 the requirements for such a request must be in writing, contain a reasonable description of the records and be over the signature of the requestor.

2. Indicate how, by whom, and for what purposes the information is to be used; indicate actual use the agency has made of the information received from current collection.

The information is collected from patients. VA personnel complete 50% of the total number of information collections and the patient must simply sign and date the form. Patients complete the remaining 50% of the information collections. The information is usually handwritten. If VA did not collect this information, the information could not be released from these patient records nor could an individual receive a copy of their health information. This would have a negative impact on patients who need and want information released to private insurance companies, physicians and other third

parties. This would also have a negative impact on patients who need a copy of their health information for their own personal purposes.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g. permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also described any consideration of using information technology to reduce burden.

In accordance with the Government Paperwork Elimination Act (GPEA) and upon OMB approval, VA Forms 10-5345 and 10-5345a and the 10-5345a-MVH will be posted on VA's Forms Internet website allowing the public to complete the forms electronically. Thus, we are complying with the intent of GPEA. Until VA implements electronic signatures, this information collection cannot be submitted electronically. Website information indicates that approximately 16% of 10-5345 and 28% of 10-5345a are accessed from the website.

4. Describe effort to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

In the past, VA attempted to combine VA Forms 3288 and 10-5345. VA's General Counsel determined that the combined forms would not meet the requirements of the Paperwork Reduction Act of 1995. The incorporation of the necessary requirements of both forms would make the combined form difficult to understand. Veterans seeking disclosure to a third party may unintentionally and unnecessarily complete portions of the form which relate to records subject to 38 U.S.C. 7332 or may mistakenly believe that the prohibition on redisclosure of 7332-protected records may apply to records that are not protected by this statute. It was therefore recommended that VA keep two separate releases of information authorization forms. VA Form 3288 is for general release and VA Form 10-5345 is specifically for release of health information including drug and alcohol abuse, sickle cell anemia and HIV information. The separate forms will assist the patient in giving informed consent and reduce the administrative paperwork burden on the public. VA Form 10-5345 will no longer be used when patients request copies of their own records. VA Form 10-5345 is an authorization form for the release of information that has to meet content requirements set forth by the HIPAA Privacy Rule; while VA Form 5345a and VA Form 10-5345a-MHV is a written request that only needs to describe the records requested and be signed by the individual. The separate forms will assist the patient when they are requesting their own medical records.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

No small businesses or other small entities are impacted by this information collection.

6. Describe the consequences to Federal program or policy activities if the collection is not conducted or is conducted less frequently as well as any technical or legal obstacles to reducing burden.

VA would not be responsive to the needs of the patient and to the legal requirement for the release of information or for providing patients copies of their own records if information were collected less frequently.

7. Explain any special circumstances that would cause an information collection to be conducted more often than quarterly or require respondents to prepare written responses to a collection of information in fewer than 30 days after receipt of it; submit more than an original and two copies of any document; 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 and require the use of a statistical data classification that has not been reviewed and approved by OMB.

There are no such special circumstances.

8. a. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the sponsor's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the sponsor in responses to these comments. Specifically address comments received on cost and hour burden.

The notice of Proposed Information Collection Activity was published in the Federal Register on September 9, 2009, pages 46484-46485. We received no comments in response to this notice.

b. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, clarity of instructions and recordkeeping, disclosure or reporting format, and on the data elements to be recorded, disclosed or reported. Explain any circumstances which preclude consultation every three years with representatives of those from whom information is to be obtained.

The legal need for a signed authorization or consent to release information mitigates against consultation. However, the form has been designed to impose the least possible burden on the public. Additionally, outside consultation is conducted with the public through the 60- and 30-day Federal Register notices.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

No payment or gift is provided to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statue, regulation, or agency policy.

Assurances of confidentiality are contained in the VHA Notice of Privacy Practices and 38 U.S.C. Sections 5701 and 7332. Respondents are informed that the information collected will become part of the Consolidated Health Record that complies with the Privacy Act of 1974. These forms are part of the system of records identified as 24VA19 "Patient Medical Record – VA" as set forth in the 2005 Compilation of Privacy Act Issuances via online GPO access at http://www.gpoaccess.gov/.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private; include specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

There are no questions of a sensitive nature.

12. Estimate of the hour burden of the collection of information:

a. The total number of responses is based on the results reported on the automated FOIA report. It is estimated that 1,300,000 respondents will have VA Form 10-5345 or 10-5345a completed by VA clerical personnel. In these cases, there will be no burden to the Veteran. Although, the Veteran's signature is required, this poses no burden hour. The other 600,000 will be completed by the Veteran (3 minutes). It is estimated that 700,000 My HealtheVet respondents will fill out the 5345a-MVH on line with no intervention of clerical personnel, this will require 3 minutes. Thus, the burden hours total 65,000.

	Responde	Χ		/ by	Annual Burden	
Form #	nt	Min.	Equals	60	Hours	
10-5345	300,000	3	900,000	60	15,000	
10-5345a	300,000	3	900,000	60	15,000	
			2,100,00			
10-5345a-MVH	700,000	3	0	60	35,000	
TOTAL	1,300,000				65,000	

b. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB 83-I.

This request covers three forms. See chart above.

c. Provide estimates of annual cost to respondents for the hour burdens for collections of information. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.

The cost to the respondents for completing these forms is \$975,000 (65,000 hours x \$15 per hour). We do not require any additional recordkeeping.

- 13. Provide an estimate of the total annual cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14).
 - a. There is no capital, start-up, operation or maintenance costs.
- b. Cost estimates are not expected to vary widely. The only cost is that for the time of the respondent.
- c. There are no anticipated capital start-up cost components or requests to provide information.
- 14. Provide estimates of annual cost to the Federal Government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operation expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

Cost to the Federal government is estimated at \$10,117,360.

Federal Government Processing/Analyzing Costs for both 10-5345, 10-5345a and 5345a-MHV										
				Response		Minute	÷ by			
			Salary	S	Equals	S	60	Total		
Printing forms	3,000							\$3,000		
Mail for										
consent	400,000*	\$0.44						\$176,000		
	1,000,00									
Mail response	0	\$0.92						\$920,000		
				\$43,446,00						
GS 5/5 Clerk, mail outgoing		\$16.71	2,600,000	0	2	60	\$1,448,200			
GS 5/5 clerk assist patient, identify				\$43,446,00						
material , process			\$16.71	2,600,000	0	10	60	\$7,241,000		
10% GS 9/5 supervisory compliance										
review			\$25.32	260,000	\$6,583,200	3	60	\$329,160		
								\$10,117,36		
TOTAL							0			
* approximately 200/ are obtained				•		•		•		

^{*} approximately 20% are obtained from web

15. Explain the reason for any program changes or adjustments reported in Items 13 or 14

VA erroneously included burden hours for consent forms that only required respondent's signature and over estimated the burden hours for VA Forms 10-5345 and 10-5345a which cost a decrease in burden. The increase in burden is due to the inclusion of VA Form 10-5345a-MHV (My HealtheVet).

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time

schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

There are no plans to publish the results of the information collected.

17. If seeking approval to omit the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

We request approval to omit the expiration date for the OMB approval. Since these forms are stocked at each field facility and the Forms and Publications Depot, displaying the expiration date would result in the waste of existing stock every three years. VA seeks to minimize the cost to itself of collecting, processing and using the information by not displaying the expiration date. For the reasons stated, VA continues to seek an exemption that waives the displaying of the expiration date on the VA Form. Additionally, since we will accept older versions, it is possible for a respondent to become confused when they see a form showing an expired OMB approval.

18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB 83-I.

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

No statistical methods are used in this data collection.