

**REQUEST FOR AND AUTHORIZATION TO RELEASE
MEDICAL RECORDS OR HEALTH INFORMATION
OMB 2900-0260**

VA Form 10-5345:	Request For and Authorization to Release Medical Records or Health Information
VA Form 10-5345A:	Individuals' Request For a Copy of Their Own Health Information
VA Form 10-5345 A-MHV:	(My HealtheVet) Individuals' Request For A Copy of Their Own Health Information
VA Form 10-0525A:	Restriction of the Release of Individually-Identifiable Health Information through Nationwide Health Information Network (NwHIN)
VA Form 10-0485:	Request For and Authorization to Release Protected Health Information to Nationwide Health Information Network

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. As it pertains to VA Form 10-0485, exchange of protected health information (PHI) between VA approved Nationwide Health Information Network participants, this special authorization must indicate the name of the requesting participating organization permitted to make the disclosure, the name of the individual or organization to which 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 authorization is subject to revocation and the date upon which the authorization will expire if not revoked before. VA Form 10-5345 is used for this purpose.

- a) **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.

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- b) **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.
- c) **VA Form 10-0525a** will be used to allow VA to capture the Veteran's request to restrict the sharing of electronic health information through the NwHIN. A patient has the right to request VHA to restrict its use or disclosure of individually-identifiable health information. In order to do this the patient must submit their request in writing. Title 38 Code of Federal Regulations (CFR) §1.526, Copies of Records and Papers states "Any person desiring a copy of any record or document in the custody of the Department of Veterans Affairs, must make written application for such copy to the Department of Veterans Affairs installation having custody on the subject matter desired stating specifically: (1) The particular record or document the copy of which is desired..., (2) the purpose for which such copy is desired to be used."
- d) **VA Form 10-0485** is used solely for the exchange of PHI between VA approved Nationwide Health Information Network participants. Written patient authorization 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 10-0485 is used solely for the electronic exchange of PHI between VA approved Nationwide Health Information Network (NwHIN) participants and VA.

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.

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 disclosed electronically through the NwHIN from these patient records. This would have a negative impact on patients who need and want information released to their private healthcare providers who are NwHIN participants. Currently, the Veteran must provide their information to VA in order to authorize their participation in the Virtual Lifetime Electronic Record (VLER) program through the NwHIN. The Veteran's information is then entered into the Veterans Authorization and Preferences (VAP) system, and is correlated with their private healthcare providers through the NwHIN, such that the exchange of patient information may commence. This exchange of patient information has been shown to provide benefits to the patient, private healthcare providers and to the VA, in that the health information is more readily accessible and

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can eliminate the need to do repeat or unnecessary procedures, provide up-to-the-minute information on current medications and allergies, medical history and ancillary testing results allowing the provider to make more informed, timely decisions affecting patient care.

As per VA Form 10-0525a, the information is collected from patients in order to grant their restriction requests. 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 Veteran would not have the ability to exclude NwHIN participants from sharing their electronic health information, as the current process is for the Veteran to complete VA Form 10-0485 for the sharing of their electronic health information with all NwHIN participants, or to not be a participant in the VLER program through the NwHIN and thus no information could be disclosed electronically through NwHIN from these patient records. This would have a negative impact on patients who need and want information released to their specific NwHIN participants.

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.

VA Forms 10-5345a and the 10-5345a-MVH are being posted on VA's Forms Internet website allowing the public to complete the forms electronically. 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.

VA Form 10-5345 and 10-0525a will be posted on VA's Forms Internet website allowing the public to complete the forms electronically through the eBenefits Portal. It will also be made available in iMedConsent, which is a class 3 software solution by Dialog Medical which has been deployed nationwide in VA Medical Centers to manage the procedure consent process, and the VA Medical Centers provide the Veteran with access to complete and sign the form on the iMedConsent electronic signature pad, eliminating the need for manual completion of the paper form, which is then automatically stored in the Veteran's electronic medical record. This process has been successful in providing Veterans without computer access the opportunity to sign-up 'electronically' for VLER at the VA Medical Centers, and by adding VA Form 10-0525a, the Veterans will also be able to have their restriction requests processed electronically.

VA Forms 10-0485 will be posted on VA's Forms Internet website allowing the public to complete the forms electronically through the eBenefits Web Portal. Once the Veteran obtains 'Level II authentication', they can log in to their secured account in the eBenefits Web Portal, and complete and submit all VLER-related documents electronically. VA Form 10-0485 has also been made available for use with iMedConsent, which is a class 3 software solution by Dialog Medical which has been deployed nationwide in VA Medical Centers to manage the procedure consent process, and the VA Medical Centers provide the Veteran with access to complete and sign the form on the iMed electronic signature pad, which eliminates the need for manual completion of the paper form, which is then automatically stored in the electronic medical record. This process has been successful in providing Veterans without computer access the opportunity to sign-up 'electronically' for VLER at the VA Medical Centers. In accordance with the Government Paperwork Elimination Act (GPEA) we are complying with the intent of GPEA on all data collections.

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.

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.

VA attempted to utilize VA Form 10-5345 for the Veterans who endorsed the sharing of their health information via the VLER program through the NwHIN, however the form required significant time and attention to detail in order to provide adequate information such that the patient could become a participant in the VLER program. This form also only acknowledged the current existence of the 38 U.S.C. 7332-protected conditions, and the VA does not have a mechanism in place to review each patient's medical record prior to disclosure to determine the presence of any of these conditions, and to ensure that a valid authorization to disclose this information is in place, such that if a 7332-protected condition became relevant to a current VLER participant, there would be no way to determine the existence of that condition(s) in order to stop the participation in the VLER program in order to obtain a new authorization to include the authority to share information relevant to the 7332-protected conditions.

There is no automated mechanism to review patient health records for the inclusion of these protected conditions, and while a manual review process was attempted in the early stages of the VLER, the continuance of this manual process would be insurmountable considering the astronomical number of Veterans estimated to enroll in the VLER program in future months. VA's attempt to use VA Form 10-5345 also resulted in the receipt of numerous invalid authorizations, in that the form was deemed to be difficult to understand and complete and prone to errors and omissions when completed independently by the patient in the first VLER pilots of the program. Thus it was determined that a need existed to develop a user-friendly, easy-to-complete form that would meet necessary guidelines while providing the desired authorization to participate in the VLER program clearly and concisely for the Veteran's completion.

Currently there is not a restriction form for use. Therefore there is not duplication of any effort with form 10-0525a.

VA Form 10-0485 is specifically for release of health information including drug and alcohol abuse, sickle cell anemia and HIV information that is present now or may be present in the future for a period

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of five years, and completion of this form will assist the patient in giving informed consent and reduce the administrative paperwork burden on the public

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 the ability to enroll in the VLER program per Federal mandate by President Obama if the information was not collected or was collected less frequently. VA would not be responsive to the needs of the patient and to the legal requirement for the opportunity for the patient to request a restriction of their information.

VA would not be responsive to the needs of the patient and to the legal requirement for the opportunity for the patient to request a restriction of their information with VA forms 10-0525a.

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 July 19, 2012, pages 42555-42256. 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.

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The legal need for a signed authorization or consent to, release or restrict release of information mitigates against consultation. However, the form has been designed to impose the least possible burden on the public.

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 privacy, to the extent permitted by law, provided to respondents and the basis for the assurance in statute, 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" and VA system of records 168VA10P2 "Virtual Lifetime Electronic Record (VLER) 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 based on the results reported on the automated FOIA report is 2,600,000. It is estimated that 1,300,000 respondents will have VA Form 10-5345 or 10-5345a completed by VA clerical personnel. Although, the Veteran's signature is required, in these cases, there will be no burden to the Veteran. Out of the remaining 1,300,000, 600,000 will be completed by the Veteran (10-5345, 2 minutes and 10-5345a, 3 minutes). It is estimated that 700,000 My HealthVet respondents will fill out the 5345a-MVH on line with no intervention of clerical personnel, this will require 3 minutes.

The total number of responses based on the results reported by the VLER program is 2,000. It is estimated that 1000 of those respondents will have VA Form 10-0525a completed by VA ROI clerical personnel. In these cases, although, the Veteran's signature is required, there will be no burden to the Veteran. From the remaining 1000, 500 will be completed by the Veteran (3 minutes). It is estimated that the other 500 will be completed in the ebenefits portal with no intervention of clerical personnel, this will require 3 minutes.

The total number of responses based on a query from the VLER sites is 100,000. It is estimated that 90,000 respondents will have VA Form 10-0485 completed by VA ROI personnel. In these cases, although, the Veteran's signature is required, there will be no burden to the Veteran. The other 9,000 will be completed by the Veteran (3 minutes). It is estimated that 1,000 ebenefits for iMed Consent respondents will fill out the 0485 on line with no intervention of clerical personnel, this will require 3 minutes.

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Form #	Respondent	X Min.	Equals	/ by 60	Annual Burden Hours
10-5345	300,000	2	600,000	60	10,000
10-5345A	300,000	3	900,000	60	15,000
10-5345a-MVH	700,000	3	2,100,000	60	35,000
10-0525A	1000	3	3000	60	50
10-0485	10,000	3	30,000	60	500
TOTAL	1,311,000				60,550

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 \$908,250 (60,550 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 \$13,676,312.75.

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Federal Government Processing/Analyzing Costs for both 10-5345, 10-5345a and 5345a-MHV								
			Salary	Responses	Equals	Minutes	÷ by 60	Total
Printing forms	3,000							\$3,000
Mail for consent	400,000*	\$0.44						\$176,000
Mail response	1,000,000	\$0.92						\$920,000
GS 5/5 Clerk, mail outgoing			\$16.71	2,600,000	\$43,446,000	2	60	\$1,448,200
GS 5/5 clerk assist patient, identify material , process			\$16.71	2,600,000	\$43,446,000	10	60	\$7,241,000
10% GS 9/5 supervisory compliance review			\$25.32	260,000	\$6,583,200	3	60	\$329,160
TOTAL								\$10,117,360
* approximately 20% are obtained from web								

Federal Government Processing/Analyzing Costs for VAF 10-0525a								
			Salary	Responses	Equals	Minutes	÷ by 60	Total
Printing forms	1,500							\$1,500
Mail for consent	500	\$0.44						\$220
Mail response	200	\$0.92						\$184
GS 5/5 Clerk, mail outgoing			\$16.71	500	\$8,355	2	60	\$278.50
GS 5/5 clerk assist patient, identify material , process (Walk-in)			\$16.71	500	\$8,355	5	60	\$696.25
TOTAL			33.42	1000	16,710	7	120	\$2878.75

Federal Government Processing/Analyzing Costs for VAF 10-0485								
			Salary	Responses	Equals	Minutes	÷ by 60	Total
Printing forms	100,000							\$100,000
Mail for 0485 authorization	100,000	\$0.44						\$44,000
Mail response	40,000	\$0.92						\$36,800
GS 5/5 Clerk, mail outgoing			\$16.71	100,000	\$1, 671,000	2	60	\$55,700
GS 5/5 clerk assist patient, identify material , process (Walk-in)			\$16.71	50,000	\$835,500	5	60	\$69,625
Contracted staff								3,249,949
TOTAL								\$3,556,074

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

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VA Forms 10-0525A and 10-0485 are new forms that contribute to the Program Change and increase in burden hours. Also, the time to complete VA Form 10-5345 was reduced from 3 minutes to 2 minutes.

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.