**SUPPORTING STATEMENT FOR 2900-0556**
**VA Form 10-0137, Advanced Directive:**
**Living Will and Durable Power of Attorney for Health Care**

## A. JUSTIFICATION

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

This form is for the purpose of documenting a VA (Department of Veterans Affairs) patient's specific instructions about health care to be carried out in the event the patient is no longer competent or able to give those instructions or make those choices verbally. Joint Commission standards require, as a part of patient's rights, that all patients are afforded the opportunity to accept or refuse health care, and that the ethical principle of patient autonomy is respected in all circumstances. VHA Handbook 1004.1, entitled Informed Consent for Clinical Treatments and Procedures, elucidates the principle of patient autonomy in health care determinations. 38 USC § 7331 and 38 CFR § 17.32 further codify these patient rights and organizational obligations.

### 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 purpose of collecting the information is to record a VA patient's specific instruction about future health care decisions in the event the patient no longer has decision-making capacity. The information will be used by health care professionals to make treatment decisions for patients. There is no consequence to any federal program or policy activity whether or not the information is collected. There will however, be two significant impacts if there is no mechanism to allow patients to express treatment preferences in advance. 1) Accreditation of all VA hospitals will be in jeopardy, and 2) VA patients will, by omission, be treated unethically. In other words, the VA standard of care *vis a vis* the ethical principle of patient autonomy will not measure up to the community standard of care, nor will it reflect statutory provisions in the states in which patients live, which provide for the opportunity to execute these type of documents.

### 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 is implementing electronic support for patient decision making at VA health care facilities nationwide. This would enable providers to enter information about patients' wishes with respect to future health care directly into the health record rather than scanning a paper document into the system. The patient would sign with an electronic key pad and a copy could be printed and provided to the patient. This will reduce the need for paper files and storage and ensure more timely and accurate entry of patients' advance directives into the electronic health record system. Unfortunately, however, this does not decrease the reporting burden.

**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.**

There is no duplication as the form is used only for patients who have not already had such documents drafted or executed through some other mechanism and elect to do so upon admission to a VA medical center. Similar information, if available will be used, and the form will not be executed for the individual in question. Not all patients have availed themselves of the opportunity to execute these documents, and therefore it is incumbent on VA hospital staff to provide this opportunity. The form needs to be available for patients who have not executed similar documents, but will not be used for patients who have such documents already in existence.

**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.**

Collection occurs at admission to a VA medical center. The patient is asked if such a document exists and if not is given the opportunity to execute one. Less frequent collection would potentially deprive patients of the opportunity to exercise autonomy in the determination of their health care.

**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 May 14, 2008 (Volume 73, Number 94, Page 27894). 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.**

All of the 50 U.S. States have statutes that acknowledge patients' rights to express their wishes with regard to future health care in an advance directive. Most provide specific forms for these purposes. Examples from several States were used as resource material together with extensive consultation with VA General Counsel, providers and patients to develop the form which is available across the national VA health care system for use by veterans. Additionally, the 60- and 30-day publication in the Federal Register provides the opportunity for stakeholder input.

**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.**

Respondents are informed that the information collected will become part of the patient's Health Record which complies with the Privacy Act of 1974. The form is part of the system of records identified as 24VA19 "Patient Medical Record – VA" as set forth in the 2003 Compilation of Privacy Act Issuances via online GPO access at http://www.access.gpo.gov/su_docs/aces/2003_pa.html

**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 specific questions of a sensitive nature. However, some consider the subject of advance health care planning and the use of advance directives to document a person's wishes with respect to future health care to be a sensitive topic. Without this data collection patients would potentially be deprived of the opportunity to exercise autonomy in the determination of their health care.

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

We estimate a burden of 171,811 hours (343,622 respondents completing the form once annually x 30 minutes). The number of forms is estimated based on facilities' orders for forms plus downloading of the electronic form, with an estimated 10% overstocking. The time estimated to complete the form is based on clinical experience.

**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 only one form.

**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.**

Cost to the public is estimated at $2,577,165 (171,811 hours x $15.00 per hour)

**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 $6,379,342. This is based on the 30 minutes the health care provider (generally a nurse or social worker averaging $37.13 per hour) spends explaining the Advance Directive form to the patient (343,622 x 30 min @ $37.13/hr).

**15. Explain the reason for any program changes or adjustments reported in Items 13 or 14 of OMB 83-I**

All changes are attributable to an adjustment. The number of veterans who complete VA advance directive form has increased as attention is focused on this subject and the aging population takes longer to complete the form.

**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.**

VA requests approval to omit the expiration date for the OMB approval on the VA Form 10-0137. Since this form is 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. Since the form has not changed, it is possible for a respondent to become confused when they see a form showing an expired OMB approval. Therefore, VA seeks to minimize its 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.

**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.