SUPPORTING STATEMENT FOR 2900-0556
VA Form 10-0137, Advance 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.

VA Advance Directive: Durable Power of Attorney for Health Care and Living Will (VA Advance Directive) is the Department of Veterans Affairs (VA) recognized legal document that permits VA patients to designate a health care agent and / or specify future health care preferences. The VA Advance Directive is invoked if a patient becomes unable to make health care decisions for him or herself. Use of the VA Advance Directive is specified in VHA Handbook 1004.02, Advance Care Planning and Management of Advance Directives. Veterans' rights to designate a health care agent and specify health care preferences in advance are codified in 38 CFR 17.32. This regulation also obligates VA to recognize advance directives and to use the information contained therein when health care decisions must be made for a patient that has lost decision making capacity. Use of advance directives is a well established standard within clinical practice in the U.S. Offering the opportunity to complete an advance directive and the requirement to honor such documents is supported by Joint Commission standards and the Patient Self Determination Act (applicable to Medicare providers.) Use of advance directives is also consistent with the health care ethics standard that patients have autonomy in health care decision making and have a right to control what is done to them in a medical setting.

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.

Veteran patients use the VA Advance Directive to designate a health care agent and / or record their future health care preferences. Completion of an advance directive by a VA patient is entirely voluntary. The decision to complete an advance directive has no bearing on a patient's right or ability to access VA health care. If a patient completes an advance directive and the completed document is provided to a VA practitioner, the information it contains is used to identify the appropriate health care decision maker and to inform decisions about the patient's care. Information contained in the VA Advance Directive is used routinely in VA to help surrogates and clinicians decide what treatments or procedures to provide to patients who have lost decision making capacity.

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 has implemented electronic support for patient decision making throughout VA's network of hospitals and clinics through the use of iMedConsent. The computer program allows clinicians to access the VA Advance Directive on a computer screen, walk the patient through the document in real time, work with the patient to complete the document in electronic form, capture the patient's signature on an electronic signature pad, and file the completed document in the patient's electronic medical record. The use of iMedConsent for this purpose shifts the burden of completing the VA Advance Directive from the patient to the provider. However, there is little practical reduction in burden to patients because the clinician must interact with the patient throughout the entire process of completing the electronic form in iMedConsent.

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.

A properly executed advance directive is recognized in a court of law as a valid expression of a patient's wishes regarding future health care. Other means of documenting health care preferences, such as including a chart note in the medical record, are not generally accorded the same weight in a court of law as a properly executed advance directive. Similar information may also be recorded in various other advance directive documents that are recognized by law in different States. VA recognizes and honors State-recognized advance directives, but these documents differ widely from State to State, and do not generally collect the same information as the VA form. In addition, they may contain information that is inconsistent with VA regulation and policy. The VA Advance Directive gives patients a uniform legal standard that is well recognized and understood by practitioners throughout VA in more than 1500 sites of care across the country.

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.

Completion of an advance directive is completely voluntary. A VA patient may complete and submit a form as often as he or she wishes. Or, a VA patient may choose to never complete such a form. The decision to complete an advance directive has no bearing on a patient's right or ability to access VA health care. If a patient loses decision making capacity and does not have an advance directive, other VA policy and regulation guide health care decision making for that patient. However, completion and filing of an advance directive with VA is the only means a patient has to ensure that his or her health care preferences are honored throughout the VA health care system.

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.

Completion of an advance directive is completely voluntary. A VA patient may complete and submit a form as often as he or she wishes. Or, a VA patient may choose to never complete such a form. VA staff is required to ask patients whether they have an advance directive or wish to complete an advance directive as a routine administrative matter. Such screening for an advance directive is required upon:

(1) Check-in for a patient's first primary care appointment, unless there is documentation of advance directive screening within the last year;
(2) Each admission to a VHA inpatient facility (including hospital, nursing home, or domiciliary facility); and
(3) Each admission to home care or hospice care.

Peer reviewed studies have shown that patients' preferences about future health care are influenced by their current health status and their experience with serious diseases and conditions. Given this propensity for patients' perceptions to change over time and in particular to change as they become ill, the

current screening schedule was established to help ensure that Veterans are reminded regularly about their right to complete an advance directive, particularly during times when they may be reconsidering the kind of care they wish to receive.

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 April 13, 2011, pages 20822-20823. 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. Many 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 VA form which is available across the national VA health care system for use by veterans. The language of the form has been updated to reflect 6th grade readability level.

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.

Respondents are informed that the information collected will become part of the patient's Health Record which 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 2003 Compilation of Privacy Act Issuances via online GPO access at http://www.gpoaccess.gov/privacyact/2003.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 people 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. In respect for diversity, this form provides patients with the option of using open text space to state individualized preferences for care that are not listed elsewhere in the document; individualized preferences might be social, cultural, or faith-based

preferences or specific treatments like pain medications. 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

There is no change in burden.

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 are not seeking approval to omit the expiration date for 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.