Home Monitoring for Early Detection of Chronic Disease Exacerbation.

OMB No. 2900-0770
Estimated Burden: 110 minutes
Expiration Date: 9/30/2020

The Paperwork Reduction Act of 1995: This information is collected in accordance with section 3507 of the Paperwork Reduction Act of 1995. Accordingly, we may not conduct or sponsor and you are not required to respond to, a collection of information unless it displays a valid OMB number. We anticipate that the time expended by all individuals who complete this survey will average 45.83 minutes. This includes the time it will take to follow instructions, gather the necessary facts and respond to questions asked. Customer satisfaction is used to gauge customer perceptions of VA services as well as customer expectations and desires. The results of this telephone/mail survey will lead to improvements in the quality of service delivery by helping to achieve services. Participation in this survey is voluntary and failure to respond will have no impact on benefits to which you may be entitled.

Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback" (OMB Control Number: 2900-0770)

TITLE OF INFORMATION COLLECTION: Home Monitoring for Early Detection of Chronic Pulmonary Disease Exacerbation (COPD).

PURPOSE:

The purpose of this study is to learn if sensors are able to detect early signs of chronic disease flare-up or worsening of symptoms. If the sensors are able to detect changes in your health, it will provide an opportunity to get medical help sooner and for you to avoid having to go to the emergency room or be hospitalized.

DESCRIPTION OF RESPONDENTS:

Veterans with the chronic condition of chronic obstructive pulmonary disease (COPD) – anticipate 25 respondents.

TYPE OF COLLECTION: (Check one)

[ ] Customer Comment Card/Complaint Form
[ ] Usability Testing (e.g., Website or Software)
[ ] Focus Group
[ ] Customer Satisfaction Survey
[ ] Small Discussion Group
[X] Other: Surveys & Interviews

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

Name: Sherry Ball, PhD

To assist review, please provide answers to the following question:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? [X] Yes [ ] No
2. If Yes, will any information that is collected be included in records that are subject to the Privacy Act of 1974? [ ] Yes [X] No
3. If Yes, has an up-to-date System of Records Notice (SORN) been published? [ ] Yes [ ] No

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [] Yes [X] No

BURDEN HOURS

Category of Respondent	**No. of Respondents**	**Participation Time**	**Burden (Hours)**
Individual	25	1 interview x 45 minutes	18.75
Individual (SF 36 Quality of Life)	25	1 survey x 15 minutes	6.25
Individual (St. George's Respiratory)	25	1 survey x 45 minutes	18.75
Individual (PHQ8)	25	1 survey x 5 minutes	2.08
Totals	**25**	**110 minutes**	**45.83 (46 Hours)**

FEDERAL COST: The estimated annual cost to the Federal government is $0

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?

[X] Yes [ ] No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

The VA study staff will identify potential subjects with a diagnosis of Chronic Obstructive Pulmonary Disease (COPD) and/or Heart Failure (HF) under treatment for COPD and/or HF through review of clinic appointment lists and the Chronic Disease Registry. Once a potential subject is identified, the VA study staff will utilize CPRS to review the electronic health record (EHR) for eligibility determination. The review will look at his/her problem list and, if necessary, notes and/or previous admission history of present illness notes will be reviewed to further determine eligibility and comorbidities. Once potential eligibility is determined, the VA study staff member will contact the potential subject either via letter or approach in waiting room, follow up with a phone call to arrange a convenient time and place to explain the study and obtain written consent in a private space. Should a potential subject be hospitalized, a VA study staff member will approach the potential subject in-hospital, at a time that does not interfere with patient care or patient sleep to discuss the project. Study objectives and inclusion and exclusion criteria will also be presented to pulmonary clinic teams. These clinical teams will receive VA study staff contact information for questions or concerns.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)
   - [ ] Web-based or other forms of Social Media
   - [X] Telephone
   - [X] In-person
   - [ ] Mail
   - [ ] Other, Explain
2. Will interviewers or facilitators be used? [X] Yes [ ] No

Please make sure that all instruments, instructions, and scripts are submitted with the request.