Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback" (OMB Control Number: 0955-0005))

TITLE OF INFORMATION COLLECTION: Office of the National Coordinator for Health Information Technology (ONC HITECH) Electronic Clinical Quality Measure Development (eCQM) Focus Groups to Inform Functional Status Assessment and Goal Achievement for Patients with Congestive Heart Failure (FSA CHF) Specification

PURPOSE:

The purpose of the provider and patient focus groups is to gather information from both the patient and clinician perspective that can help inform the continued evolution of the FSA CHF eCQM specification proposed for inclusion in Stage Three of the CMS Meaningful Use Program (MU-3). While the proposed outcome measure for MU-3 expands upon the initial FSA CHF process measure included in MU-2, there is a need to learn more about approaches and experiences with shared physician-patient goal setting in general, and more specifically, as it relates to the use of specific functional status assessment tools in an EHR (electronic health record) or EMR (electronic medical record). Further clarification of the clinical workflow processes and technical implementation of how goal setting with congestive heart failure patients is conducted in the clinical setting will directly inform key measure properties including data capture, availability, and accuracy. Moreover, the EHR systems and quality data model standards add technical constraints to how information, once captured, can be integrated into EHR systems. Insight from both focus groups will aid in understanding technical constraints and lead to smoother implementation of a usable and well-informed Functional Status Assessment for Patients with Congestive Heart Failure outcome measure.

The intent of the provider focus groups will be to provide an opportunity to better understand clinical workflow of practicing physicians and to discuss viable approaches to a shared physician-patient goal setting process. The intent of the patient focus groups will be to listen to feedback from the patient and family perspective to better understand how Heart Failure affects the individual lives of patients with this condition, and what is most important for them to be able to change or improve upon, as they manage their condition and care process with their cardiologist and clinical care teams.

DESCRIPTION OF RESPONDENTS:

Provider Focus Group Participants

Prior research and collaboration in the area of Functional Status Assessments and Patient-Reported Outcomes specific to patients with Congestive Heart Failure has identified a number of sites where innovative approaches to clinical care are continuing to evolve and be tested. Our team is planning to work with several of these sites to engage cardiologists and the clinical care team in providing insight and perspective in shared-goal setting. Ideally we would like to convene a group of 10-12 respondents, representing a cross-section of experience, including physicians (e.g., cardiologists and primary care physicians treating cardiology patients, gerontologists, medical director for quality), as well as additional clinicians who would be involved across the clinical care team (e.g. quality review coordinator, quality manager, risk manager, social worker, functional status assessment research coordinator, IT, medical records, clinical informaticist).

Patient Focus Group Participants

Our approach to targeting patient focus group participants is to work with clinical practice teams across several geographic locations to identify patients who meet the following criteria:

1. Diagnosed with active heart failure
2. Age 65 years or older
3. New York Heart Association (NYHA)
   a. Class I (10% of patients);
   b. II/III (80% of patients);
   c. IV (10% of patients)
4. The patient cannot have had a heart transplant or LVAD

From this universe of patients we are looking for those willing to share their perspective on goal setting, including experiences in jointly setting goals with their clinician, or thinking through goals they would set for themselves as a part of their care delivery. We are also interested in learning reasons why patients might not share their perspective with their clinician or care team.

TYPE OF COLLECTION: (Check one)

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

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. – around the CONCEPT not policy
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: **Michael Yesenko**

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

Personally Identifiable Information:

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

Gifts or Payments:

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

Provider Focus Groups – no incentive payment to participants
Patient Focus Groups – no incentive payment to participants

BURDEN HOURS

Category of Respondent	No. of Respondents	Participation Time	Burden
Individual – Clinicians participating in the Provider Focus Group	60	2 hours	120 hours
Individual – Patients participating in the Patient Focus Group	40	2 hours	80 hours
Totals			**200 hours**

FEDERAL COST: The estimated annual cost to the Federal government is 200 hours and $15,600 (covered through the existing ONC HITECH eCQM contract)

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?

Clinical staff at testing sites will identify patients who have an active diagnosis of Heart Failure and are at least 65 years of age. The staff will contact individuals to introduce the patient focus group team and ask if they are interested. The patient focus group team will contact those who have indicated interest in participation. Further detail can be found in the attached Patient Recruitment Protocols.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)
   [ ] Web-based or other forms of Social Media
   [ ] 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. Instructions for completing Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback"

TITLE OF INFORMATION COLLECTION: Provide the name of the collection that is the subject of the request. (e.g. Comment card for soliciting feedback on xxxx)

PURPOSE: Provide a brief description of the purpose of this collection and how it will be used. If this is part of a larger study or effort, please include this in your explanation.

DESCRIPTION OF RESPONDENTS: Provide a brief description of the targeted group or groups for this collection of information. These groups must have experience with the program.

TYPE OF COLLECTION: Check one box. If you are requesting approval of other instruments under the generic, you must complete a form for each instrument.

CERTIFICATION: Please read the certification carefully. If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved.

Personally Identifiable Information: Provide answers to the questions. Note: Agencies should only collect PII to the extent necessary, and they should only retain PII for the period of time that is necessary to achieve a specific objective.

Gifts or Payments: If you answer yes to the question, please describe the incentive and provide a justification for the amount.

BURDEN HOURS:
Category of Respondents: Identify who you expect the respondents to be in terms of the following categories: (1) Individuals or Households; (2) Private Sector; (3) State, local, or tribal governments; or (4) Federal Government. Only one type of respondent can be selected per row.
No. of Respondents: Provide an estimate of the Number of Respondents.
Participation Time: Provide an estimate of the amount of time (in minutes) required for a respondent to participate (e.g. fill out a survey or participate in a focus group)
Burden: Provide the Annual burden hours: Multiply the Number of Respondents and the Participation Time then divide by 60.

FEDERAL COST: Provide an estimate of the annual cost to the Federal government.

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. Please provide a description of how you plan to identify your potential group of respondents and how you will select them. If the answer is yes, to the first question, you may provide the sampling plan in an attachment.
Administration of the Instrument: Identify how the information will be collected. More than one box may be checked. Indicate whether there will be interviewers (e.g. for surveys) or facilitators (e.g., for focus groups) used.
Submit all instruments, instructions, and scripts are submitted with the request.