U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

OFFICE OF MANAGEMENT AND BUDGET
PAPERWORK REDUCTION ACT
CLEARANCE PACKAGE

REVISED SUPPORTING STATEMENT-PART A

ACA §3004 IRF Quality Reporting Program: Program Evaluation

Supporting Statement for Paperwork Reduction Act Submissions
Part A

ACA §3004 IRF Quality Reporting Program:
Program Evaluation

A. BACKGROUND

Section 3004 of the Patient Protection and Affordable Care Act (ACA) (which added section 1886(j)(7) to the Social Security Act ("the Act")) mandated that the Centers for Medicare & Medicaid Services (CMS) establish a quality reporting program for Inpatient Rehabilitation Facilities (IRFs). Section 1886(j)(7)(C) of the Act requires IRFs to submit quality data in a time, form and manner specified by the Secretary.

Section 1886(j)(7)(A)(i) of the Act states that beginning with the FY 2014 IRF PPS annual increase factor and each subsequent fiscal year thereafter, the Secretary shall reduce such increase factor for payments for discharges occurring during such fiscal year by 2 percentage points for any IRF that fails to submit the required type and amount of quality data.

The Centers for Medicare & Medicaid Services has established quality reporting and public reporting programs for various care settings with the goal of promoting higher quality and more efficient healthcare for beneficiaries. These programs have helped focus quality improvement efforts and provide stakeholders information needed for decision-making. The overall goal for CMS is to achieve the 3 aims of the U.S. Department of Health and Human Services (HHS) as outlined in the National Quality Strategy: (1)Better Care, (2) Healthy People/Healthy Communities and (3) Affordable Care.

The following are examples of some of the healthcare services that are measured through the CMS quality measurement programs: (1) hospital inpatient services are monitored through the Hospital Inpatient Quality Reporting (IQR) Program; (2) hospital outpatient services are monitored with the Hospital Outpatient Quality Reporting (OQR) Program; and, (3) the quality of services rendered by physicians and other eligible professionals' services are monitored with the Physician Quality Reporting System (PQRS).

In addition, CMS has implemented quality reporting programs for home health agencies and nursing facilities.

B. JUSTIFICATION

1. Need and Legal Basis

The IRF Quality Reporting Program was established pursuant to section 3004(b) of the ACA, which added section 1886(j)(7) to the Social Security Act. This quality reporting program requires that IRFs report quality measure data to CMS in a time, form and manner as specified by the Secretary. Eventually, as statutorily required, CMS will publicly report the IRF quality

measure data. However, as required by 1886(j)(7)(E) of the Act, IRFs must be given the opportunity to review their quality measure data, before it is made public.

CMS has experience in implementing, monitoring, and evaluating quality reporting programs. Such activities have been established for the inpatient and outpatient settings. ACA 3004 also established quality reporting programs for long term care hospitals and hospices. CMS is interested in exploring how IRF providers are responding to the new QRP and its measures. We believe that it is important to understand early trends in outcomes, to make adjustments as needed to enhance the effectiveness of the program, and to seek opportunities to minimize provider burden, and ensure the quality reporting program is useful and meaningful to the providers.

In order to implement and execute a valid and meaningful QRP program, it is essential that the data collected not only be accurate, but that CMS is able to evaluate the success of the program to determine if it is meeting its stated goals. Therefore, we believe that ongoing programmatic evaluation such as the monitoring of its processes, requirements and impact is both fundamental and essential for evaluating overall programmatic impact. In this, we believe it is important for CMS to be informed about providers' experiences related to the program.

We believe that the data collection from the IRF QRP's program evaluation activities will help inform CMS in next steps related to Monitoring and Evaluation-related activities; particularly with monitoring. It is essential to perform monitoring and evaluation (M&E) activities over the life of a program to understand how well the program is meeting its intended goals and to discover any need for program improvement. *Monitoring* (formative evaluation) is an "early warning" system for alerting CMS of both anticipated and unanticipated interim trends and patterns related to program implementation and performance in near to real time. Goals related to monitoring efforts include:

- Enabling early intervention if any changes to the program are necessary
- Determining if those implementing the program require technical assistance
- Providing stakeholders with information on early achievements

Monitoring activities are implemented at the start of a program to track the positive, negative, or unanticipated effects of the program in real time. The IRF QRP program evaluation would serve such early steps. Such first steps enable the building of trust between CMS and its stakeholders who can serve to inform CMS in its decision making about any needed changes in the QRP, as well to identify how to best meet the needs of providers in anticipation of how they will use the information gleamed from monitoring and evaluation-related activities. This survey/interview would allow for direct feedback from providers to obtain their perspective and build upon that partnership for more formal dialogue in the future, as the QRP matures. Therefore, the purpose of evaluating the IRF QRP is multi-fold, including: determining how providers are responding to the new QRP, the mechanisms utilized by providers to collect and report data (inclusive of determining the accuracy of that data), burden, practices related to data collection, use of EHRs, etc., and the overall impact and influences of the QRP on healthcare outcomes. We believe that this program evaluation is a learning opportunity for the providers and for CMS.

The methodology employed in the evaluation is the utilization of qualitative interviews (as opposed to quantitative statistical methods). In consultation with research experts, CMS has decided that at this juncture it would be meaningful to use a rich, contextual approach to evaluate the process and success of the QRP initiative. A qualitative approach uses a semi-structured interview methodology (i.e., wording and order of questions is not expected to be precisely the same for all providers). The goal of a qualitative interview process is to elicit information from participants while minimizing response bias, and allowing the subject to lead the discussion. Outlined in this PRA are nine (9) discussion topics (listed as questions), with probable follow-up topics, but each discussion is likely to take on its own characteristic. The decision to pursue this methodology (i.e., qualitative) was informed by our earlier pilot discussions with a small number of providers (i.e., less than nine) in 2013, in which we learned that providers are anxious to have their voice heard, but that they did not feel comfortable expressing themselves fully in public open door forums. Providers desired some level of confidentiality, which this methodology affords.

To perform this program evaluation activity, CMS will be seeking voluntary, provider input in this program evaluation. CMS, in collaboration with its contractor, will be reviewing the input from providers to help direct the future actions of the QRP. Voluntary participation in this phase of the evaluation of the new QRP can be beneficial to the provider facilities by lending them a voice in how the QRP continues in its implementation. We believe that this program is an opportunity for both the providers and CMS to learn. Participation by the IRF is fully voluntary with no risk of penalty if the decision is made to not participate.

2. Information Users

- Data Submitters –IRFs (participation is on a voluntary basis)
- Data Users:
  - **CMS – CCSQ / QMHAG / Division of Chronic & Post-Acute Care (DCPAC)** The intended use of the information collected is to help inform CMS of providers' experiences related to the QRPs, such as program impact related to quality improvement, burden, process-related issues, and education. This will also inform future measurement development for the IRF QRP, future steps related to data validation, as well as future monitoring and evaluation. General findings may be used to discuss CMS' future efforts in the quality reporting program.
  - **Health Care Innovation Services (HCIS)** –CMS' data analysis contractor will obtain the data on behalf of CMS and will perform the above-described program evaluation activities with the information that is obtained.

3. Use of Information Technology

The information to be collected as part of the IRF QRP's program evaluation activities will be collected using a personal interview technique (either in person or via telephone). IRF providers will not be asked to provide any information to CMS using any type of information technology.

4. Duplication of Efforts

This information collection does not duplicate any other effort.

5. Small Businesses

Participation in the evaluation activities of the IRF QRP will have little, if any, effect on IRFs that are considered to be small businesses because provider participation during this phase is completely voluntary and there will be no penalty placed on an IRF for non-participation.

6. Less Frequent Collection

Program evaluation will involve using a qualitative structured interview process to learn from providers how the QRP has impacted their service delivery; how they capture, record, and validate data; and any barriers or obstacles to data accuracy. Qualitative data involves analysis for thematic patterns and does not include statistical analysis that is associated with quantitative data methods.

7. Special Circumstances

There are no special circumstances.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 60 day Federal Register notice was published on November 22, 2013. One public comment was received in response to this PRA notice. A copy of this comment and our response thereto is included in this PRA package as a separate document.

9. Payment/Gifts to Respondents

There will be no payments/gifts to IRFs for participation. There are no penalties for non-participation.

10. Confidentiality

No patient level data will be collected as part of this process. All participants will be notified that everything they say will be confidential. Data will be treated in a confidential manner, unless otherwise compelled by law.

11. Sensitive Questions

No personal health information (PHI) will be collected as part of the process. Interview subjects will be informed that they can choose to not answer any question(s) that they feel uncomfortable answering.

12. Burden Estimates (Hours & Wages)

The following is an estimate of the estimated burden that IRF providers will incur as result of voluntary participation in the IRF Quality Reporting Program Evaluation.

1. <u>Time Burden Calculation</u>

- Number of IRFs to participate in evaluation process: 30
- Data collection method to be used: In-person or telephone interviews
- Number of staff at each IRF location to be interviewed: 2
- Job titles of IRF staff to be Interviewed:
    a. Nursing Administrator (i.e. - Director of Nursing / Nurse Manager of IRF Unit)
    b. Infection Control/Quality Assurance Coordinator (Registered Nurse)

- Number of questions to be used in interview = 9
- Estimated average time required to complete each interview question = 7 minutes

<u>Estimated Time Required to Complete Interviews of 2 IRF staff = 126 minutes</u>
9 questions per interview x 7 minutes per question = 63 minutes (Nurse Administrator)
9 questions per interview x 7 minutes per question = 63 minutes (IC/QAC Nurse)
126 minutes / 60 minutes per hour = 2.1 hours

<u>Other Estimated Burden Associated with IRF Monitoring Program = 15 minutes</u>

- Estimated time spent by IRF to arrange for participation in Program = 15 minutes (i.e. – prepare for CMS arrival at facility, Introductions to staff, explanations of interview, preparations, time between interviews, etc.)

126 minutes - Interviews of 2 IRF nurses

15 minutes - Time spent by facility to arrange for participation in program
141 minutes – Total estimated time per each IRF

141 minutes/60 minutes per hour = 2.35 hours
2.35 hours per each IRF x 30 IRFs = 71 hours across 30 IRFs to be interviewed

2. Wage Calculation

We estimate that the following tasks will be performed by the Nurse Administrator:
Estimated average time for interview by CMS representative 63 minutes

Total **63 minutes**

We estimate that the following task will be performed by the IC/QAC Nurse:
Estimated average time for preparation and interview by CMS representative 78 minutes

According to Salary.com and the U.S. Bureau of Labor Statistic, the average hourly wages for the nurses that CMS plans to interview are as follows:

Job Title	Avg. Hourly Wage	Estimated Yearly Wage
Nurse Administrator	$40.52	$84,282 per year[1]
Infection Control/ Quality Assurance Nurse	$34.78	$72,351 per year[2]

Nurse Administrator Wages:

a. Wages per Each IRF:
63 minutes / 60 minutes per hour = 1.05 hours
1.05 hrs. x $40.52 per hour = $42.55 [3]

b. Across all 30 IRFs
1.05 hours x 30 IRF = 31.5 hours
31.5 hours x $40.52 per hour = $1,276.38

Infection Control/Quality Assurance Coordinator Nurse Wages:

a. Wages Per Each IRF**:**
78 minutes / 60 minutes per hour = 1.3 hours

[1] See http://www.bls.gov/ooh/Management/Medical-and-health-services-managers.htm
[2] http://www1.salary.com/Quality-Assurance-Coordinator-Healthcare-salary.html

[3] This number is rounded to the nearest cent (i.e., $42.546).

1.3 hours x $34.78 per hour = $45.21[4]
b. Across all 30 IRFs:
1.3 hours x 30 IRF = 39 hours
39 hours x $34.78 per hour = $1356.42

Total Estimated Wages to be Incurred By Each IRF:

$ 42.55[5]	Nurse Administrator Wages
$ 45.21[6]	Infection Control/Quality Assurance Coordinator Nurse Wages
$87.76	**TOTAL**

Total Estimated Wages to be incurred across 30 Participating IRFs:

$1,276.38	Nurse Administrator Wages
$1,356.42	Infection Control/Quality Assurance Coordinator Nurse Wages
$2,632.80	**TOTAL**

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

CMS will use their data analysis contractor, HCIS to assist them with the administration of the IRF QRP Program Evaluation. CMS will incur costs associated with the work performed by this contractor. The estimated cost to the government for the work to be performed by HCIS is estimated to be $125,000.

The work to be performed by HCIS for IRF QRP Evaluation includes the following tasks: (1) to give notice and educational information to IRFs about the new IRF QRP: Program Evaluation; (2) to invite IRFs to voluntarily participate in the program; (3) to select 30 IRFs for participation in the IRF QRP: Program Evaluation; (4) to perform interviews with two nurses at each selected IRF; (5) to compile and analyze all data obtained from the staff interviews at each selected IRF; (6) to provide CMS with a report which summarizes the data obtained, then states findings, conclusions, and recommendations.

[4] This number is rounded to the nearest cent (i.e., $45.214)

[5] This number is rounded to the nearest cent (i.e., $42.546).

[6] This number is rounded to the nearest cent (i.e., $45.214)

15. Changes to Burden

This is a new data collection.

16. Publication/Tabulation Dates

CMS may use the data collected to inform the IRF QRP as it develops however, at this time the data is not intended for public display. In the future CMS may find that the publication of general findings are informative and useful for public benefit.

17. Expiration Date

Not applicable because no written materials will be disseminated to providers.