Supporting Statement – Part A

PPS-exempt Cancer Hospital Quality Reporting (PCHQR) Program

A. Background

Pursuant to section 1886(d)(1)(B)(v) of the Act as amended by section 3005 of the Affordable Care Act , starting in FY2014, and for subsequent fiscal years, PPS-exempt cancer hospitals (PCHs) shall submit pre-defined quality measures to CMS. To comply with the statutory mandate, we are implementing the PPS-exempt Cancer Hospital Quality Reporting Program (PCHQR) in our sustained efforts to improving the quality of care for inpatient cancer patients. It is our aims and goals to facilitate high quality of care in a manner that is effective and meaningful, while remaining mindful of reporting burden pose on the PCHs. Therefore, CMS intends to reduce and avoid duplicative reporting efforts whenever possible by leveraging existing infrastructure.

For the FY2014 program year, we are proposing five (5) NQF-endorsed quality measures developed by the Center for Disease Control (CDC) and American College of Surgeons'/Commission on Cancer (ACS/CoC).

MEASURE STEWART	QUALITY MEASSURES
ACS/CoC	Adjuvant chemotherapy for Stage III colon cancer (NQF#0223)
	Combination chemotherapy for AJCC T1c or Stage II or III hormone receptor-negative breast cancer (NQF#0559)
	Hormone therapy for AJCC T1c or Stage II or III hormone receptor-positive breast cancer (NQF#0220)
CDC	Health Acquired Infection (HAI) Measure Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF#0754)
	Health Acquired Infection (HAI) Measure Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF#0752)

Although PCHs have not reported on quality measures to CMS, they have some familiarity with and experience in reporting of quality data. More specifically, out of the 11 existing PCHs, 10 are currently reporting the proposed measures to the ACS/CoC. This equates to 91 percent of PCHs that already report the measures on a regular basis. Likewise; a majority of the PCHs have been submitting data to the CDC under the NHSN OMB Paperwork Reduction Act (PRA) package number 0920-0666. The fact that the majority of the PCHs have demonstrated the ability to report the measures indicates the proposed regulation does not significantly impact PCHs. We are proposing a two-step approach in data reporting. First, patient-level data will be submitted to the CDC and ACS/CoC by the PCHs. And secondly, the CDC and a CMS contractor will submit aggregated and calculated measure rates to CMS. Therefore, to minimize burden and avoid duplicative reporting efforts, PCHs only have to

submit data once to each entity.

CMS is proposing to implement some procedural requirements to meet the statutory mandate by setting boundaries and align with current quality reporting programs. These procedural requirements would involve submission of forms to comply with the PCHQR Program requirement and aligns with current CMS reporting requirements for other quality programs (i.e., Hospital Inpatient Quality Reporting, Hospital Outpatient Quality Reporting, and Hospital Value-Based Purchasing). The aforementioned forms that require clearance are the Notice of Participation (NOP), Data Accuracy and Completeness Acknowledgement (DACA), Decline Participation, Participation Withdrawal Form, and Intensive Care Unit (ICU) Location Waiver (specifically for the HAI measures) forms.

B. Justification

1. Need and Legal Basis

Section 1886(d)(1)(B)(v) in accordance with paragraph (2) of the Act requires that, for FY2014 (October 1, 2013 through September 30, 2014) and each subsequent fiscal year, each PPS-exempt cancer hospital shall submit to the Secretary data on quality measures as specified by the Secretary. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary.

In implementing the PPS-exempt Cancer Hospital Quality Reporting (PCHQR) Program, we believe that the development of a quality reporting program that is successful in promoting the delivery of high quality health care services in PCH setting is of paramount importance. Therefore in our effort to provide services to the PCHs, we are proposing some procedural requirements to ascertain that the PCHs wish to participate in the Program accept the conditions put forth to comply with our agency's reporting (procedural) requirements.

As the statute provides in section 1886(d)(1)(B)(v) in accordance with paragraph (4), in establishing the PCHQR Program, requires the Secretary to establish procedures for making public the data/measure rates submitted by PPS-exempt cancer hospitals (PCHs) under the PCHQR Program. In order for CMS to publish the measure rates, PCHs would need to pledge to participate in the PCHQR program, meaning PCHs would need to submit the Notice of Participation (NOP) form. By submitting the NOP, PCHs are pledging to participate in the PCHQR Program and shall submit the required data pertaining to the five (5) quality measures and additionally, consent to publicly report their measure rates on the Hospital Compare Web site. We are mindful and respectful that PCHs may choose not to participate or withdraw from the Program. In our effort to maintain good stewardship, we are providing some means to provide PCHs the opportunities to decline or withdraw from the Program.

As part of our procedural requirements, we are also requiring the PCHs to acknowledge and attest to the data submitted. We seek to efficiently collect information on valid, reliable, and relevant measures of quality and to share this information with the public, as provided under section 1886(d)(1)(B)(v) as amended by section 3005 of the Affordable Care Act. PCHs will

have to submit the Data Accuracy and Completeness Acknowledgement (DACA) form. In submitting this form, PCHs acknowledge that the data submitted are true, accurate, and complete. Besides submitting the DACA, PCHs are given the opportunity to submit the Intensive Care Unit (ICU) Location Waiver form. PCHs with no ICU or experiencing low case threshold to meet the inclusion criteria, as set forth by the CDC on two (2) Health Acquired Infection (HAI) measures, may request for a waiver to be excluded from data submission.

2. Information Users

- PCHs: PCH main focuses are to examine individual PCH's specific care domains and types of patients and can compare present performance to past performance with national performance norms; to evaluate the effectiveness of care provided to specific types of patients and, in the context of investigating processes of care, to individual patients; to continuously monitor quality improvement outcomes over time, and to objectively assess their own strengths and weaknesses in the clinical services they provide; and to inform the respective PCH of the care-related areas, activities, and/or behaviors that result in effective patient care, and alert them to needed improvements. Such information is essential to PCHs in initiating quality improvement strategies. They can also be used to improve PCHs' financial planning and marketing strategies.

- State Agencies/CMS: Agency profiles are used in the process to compare a PCH's results with its peer performance. The availability of peer performance enables state agencies and CMS to identify opportunities for improvement in the PCH, and to evaluate more effectively the PCH's own quality assessment and performance improvement program.

- Accrediting Bodies: National accrediting organizations such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) or state accreditation agencies may wish to use the information to target potential or identified problems during the organization's accreditation review of that facility.

- Beneficiaries/Consumers: Since November 2003, the Hospital Inpatient Quality Reporting (HIQR) Program has been publicly reporting quality measures on the Hospital Compare Web site available to consumers on www.Medicare.gov. The website provides information for consumers and their families about the quality of care provided by individual hospital, allowing them to see how well patients of one agency fare compared to other agencies and to the state and national average. The website presents the quality measures in consumer-friendly language and provides a tool to assist consumers in the selection of a hospital. Modeling after the HIQR Program, the PCHQR Program uses quality measures to assist consumers in making informed decisions when choosing a cancer hospital; to monitor the care the cancer hospital is providing; and to stimulate cancer hospital to further improve quality to identify the optimal practice.

3. Use of Information Technology

CMS is providing a secure data warehouse and use of QualityNet (QNet) Exchange Web site for storage and transmittal of the data prior to release of data to the Hospital Compare Web site. The PCHs will submit the five quality measures mentioned on page one to CDC and ACS/CoC. After the data are calculated by CDC and ACS/CoC, they will submit the calculated measure rates to CMS.

Additionally, the secure QNet Exchange Web site will store forms required for this program. The PCHs will be able to complete a Notice of Participation or indicate that they do not wish to participate via QualityNet. Samples of each of the forms, the Notice of Participation (NOP), Decline Participation, Data Accuracy and Completeness Acknowledgement (DACA), and Intensive Care Unit (ICU) Location Waiver are included.

4. Duplication of Efforts

The PCHQR Program does not impose duplicate data collection. It uses elements that are currently collected by the CDC and ACS/CoC and integrating it into our current CMS's system. Currently, under the HIQR program, hospitals (including some PCHs) are already submitting the CLABSI and CAUTI measures to CDC under the NHSN OMB Paperwork Reduction Act (PRA) package number 0920-0666. Conversely, 10 PCHs are already submitting cancer measures to ACS/CoC. In an effort to reduce burden and minimize duplicative efforts, CMS is leveraging existing infrastructure through the CDC and ACS/CoC's infrastructure.

5. Small Businesses

CMS has taken steps to reduce burden to all providers, including those that are small businesses. For example, we will be providing a help-desk hotline for troubleshooting purposes and 24/7 free information.

6. Less Frequent Collection

Unlike other existing quality reporting programs, this program is not link to any payment penalties if quality measures are not submitted. Therefore, we propose to collect data on an annual basis, which sufficiently meets the statutory mandated by the Affordable Care Act.

7. Special Circumstances

PCHs will have to abide with the reporting procedures set forth by the CDC and the CMS contractor to collect ACS/CoC quality measures.

8. Federal Register/Outside Consultation

We are proposing to solicit comments on the procedural requirements through the proposed rule. Additionally, we have been working closely with the reporting entities (CDC and CMS contractor to collect ACS/CoC) and the individual PCHs on details pertaining to the Program.

A 60-day Federal Register Notice will be published on April 13, 2012. The 60-day FR notice will be included in the NPRM that will be published on April 13, 2012.

9. Payments/Gifts to Respondents

There are no payments or gifts to respondents.

10. Confidentiality

We pledge confidentiality of patient-specific data as provided by the Privacy Act of 1974 (5 U.S.C. 552a).

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates (Hours & Wages)

Although minimal, we acknowledge that there is a small burden associated with collecting information as part of the comprehensive assessment for the PCHQR Program requirements. Our estimates of time, cost, average PCH size, and staff salaries are calculated as indicated below.

The burden estimates for data collection related to the proposed measures for the PCHQR Program are calculated for the PCHs with the following figures. There are approximately 27,273 inpatient cancer cases for all facilities annually and there are approximately 11 PCH facilities nationwide. There is an average of 2,479 PPS-exempt Cancer Hospital (PCH) Cases per Facility annually. The average time spent per each quality measure per patient chart abstraction is approximately 30 minutes (based on 2007 GAO measure abstraction work effort survey GAO-07-320). This includes an estimate of approximately 25 minutes of clinical time spent to conduct chart abstraction for each measure and approximately 5 minutes of administrative time spent to submit data from each cancer measure to the CDC and ACS/CoC. To report on all five (5) measures for chart abstraction and administrative time totals approximately 2.5 hours. Thus with 2,479 cases per facility this creates an annual burden of 68,182 annual burden hours.

Table A

Number of PCHs	**Number of Cases per PCH**	**Total Number of Cases**	**Burden Hours**	**Annual Burden Hours**
11	2,479	27,273	2.5	68,182

The PRA costs related to wages is based on an hourly rate of $29.47.[1] This calculated for the 68,182 hours for chart abstraction and data submission is $2,009,043.57 annual cost per all 11

1 Bureau of Labor Statistics: http://www.bls.gov/oes/current/oes292071.htm.

PCHs. The estimated burden for training personnel for data collection and submission for all quality measures is 96 hours per facility or 1,056 hours for all 11 PCHs. The cost for this training based on an hourly rate of $29.47 is $31,120.32 training costs for all 11 PCHs annually. The total burden estimates for all data collection and submission costs and training for all facility is $2,009,043.57 and $31,120.32 annually. The total annual cost for all the facilities for data collection, submission and training is $2,040,163.89 (See Table B).

Table B

Tasks	**Hours per PCH**	**Wage rate**	**Cost per PCH**	**Total cost for all PCH**
Data Collection and Submission	6,197.5	$29.47	$182,640.33	$2,009,043.57
Training	96	$29.47	$2,829.12	$31,120.32
Total				$2,040,163.89

The Data Accuracy and Completeness Acknowledgement (DACA) Form, Notice of Participation From, Decline to Participate Form, and Participation Withdrawal Form will be used whenever there is a change in the PCH's participation status. However, the Intensive Care Unit (ICU) Location Waiver Form will be used on every annual data submission.

13. Capital Costs

There will not be any capital cost.

14. Cost to Federal Government

The aggregated data for the PCHQR Program measures will be reported directly to QualityNet Exchange website utilizing existing system functionality and support. There will be minimal additional costs to modify existing infrastructure.

However, the labor cost is roughly estimated at $83,200 for the first year and thereafter $20,800 for subsequent years.

For initial start up staff time, it is estimated that approximately 1,040 hours/FTE. At least 2 FTEs are required, therefore, the total FTEs are 2.080 hours. After the start up, the maintenance is minimal (about 25% less) which would be approximately 520 hours.

15. Changes to Burden

Between the draft rule and the final rule, there have been minor editorial changes to the forms. The HAI form was revised to add the pediatric intensive care unit (ICU) as the new location. Also, the adult ICU and non-ICU locations have been defined. The burden has not changed.

16. Publication/Tabulation Dates

- Final rule display on August 2, 2012.
- Quality measures announcement no later than October 1, 2012.
- Deadline to complete NOP - August 15, 2013.
- Deadline to complete ICU waiver form – August 15, 2013.
- Data submission July 1, 2013 – August 15, 2013.
- Deadline to complete DACA - August 31, 2013.

17. Expiration Date

We request an exemption from displaying the expiration date because these tools will be used on a continuous basis by hospitals reporting quality data, with the exception of changes to the PCHQR Program and/or statutory mandate.